

BEFORE THE  
SCIENCE SUBCOMMITTEE  
OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: WEDNESDAY, SEPTEMBER 29, 2010  
11:30 A.M.

REPORTER: BETH C. DRAIN, CSR  
CSR. NO. 7152

BRS FILE NO.: 88383

## BARRISTERS' REPORTING SERVICE

### I N D E X

ITEM	DESCRIPTION	PAGE NO.
CALL TO ORDER		3
ROLL CALL		3
	CONTINUED DISCUSSION OF AND CONSIDERATION OF CHANGES TO EXTRAORDINARY PETITION AND GRANTS ADMINISTRATION APPEALS PROCESS	4
	DISCUSSION OF PROPOSAL FOR PROGRAMMATIC SCORING OF GRANT APPLICATIONS BY PATIENT ADVOCATE MEMBERS OF GRANTS WORKING GROUP FOR INCLUSION IN DISCUSSION AND DECISIONS REGARDING APPLICATIONS	35
	CONSIDERATION OF PROCESS FOR APPROVING USE OF UNUSED DISEASE TEAM RESEARCH AWARD GRANT FOUND FUNDS FOR RESEARCH THAT GOES BEYOND THE SCOPE OF THE ORIGINAL RFA'S	55
PUBLIC COMMENT		NONE

**BARRISTERS' REPORTING SERVICE**

1 WEDNESDAY, SEPTEMBER 29, 2010

2 11:30 A.M.

3  
4 CHAIRMAN SHEEHY: THANKS, MELISSA. AND I  
5 WANT TO THANK EVERYBODY FOR BEING ON THE CALL TODAY.  
6 I THINK WE'LL START THE MEETING. DO YOU WANT TO  
7 CALL THE ROLL.

8 MS. KING: JACOB LEVIN. MARCY FEIT.  
9 MICHAEL FRIEDMAN.

10 DR. FRIEDMAN: HERE.

11 MS. KING: BOB KLEIN.

12 CHAIRMAN KLEIN: HERE.

13 MS. KING: FRANCISCO PRIETO. ED PENHOET.  
14 PHIL PIZZO. JEANNIE FONTANA.

15 DR. FONTANA: HERE.

16 MS. KING: DUANE ROTH.

17 MR. ROTH: HERE.

18 MS. KING: JOAN SAMUELSON. JEFF SHEEHY.

19 CHAIRMAN SHEEHY: HERE.

20 MS. KING: OSWALD STEWARD. ART TORRES.

21 MR. TORRES: HERE.

22 CHAIRMAN SHEEHY: WE DON'T HAVE A QUORUM,  
23 DO WE?

24 MS. KING: NOT QUITE YET. NO. WE NEED  
25 NINE.

## BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: SO I THINK THE FIRST  
2 THING THAT WE'LL LOOK AT IS CHANGES TO THE  
3 EXTRAORDINARY PETITION POLICY/APPEALS POLICY. WE  
4 HAVE THREE OPTIONS HERE. HAVE PEOPLE HAD AN  
5 OPPORTUNITY TO LOOK THROUGH THE OPTIONS THAT -- I  
6 KNOW SOME OF THIS ARRIVED LATE. WE'VE BEEN WORKING  
7 ON THIS.

8 OPTION A IS DR. STEWARD'S OPTION,  
9 SUGGESTION, AND IT WOULD HAVE THE APPLICANT APPEND  
10 THEIR ACTUAL APPLICATION TO THEIR EXTRAORDINARY  
11 PETITION.

12 OPTION C -- OPTION B IS A PROCESS THAT  
13 PROVIDES THE BOARD WITH OFFICIAL OPTION WHEN THEY'RE  
14 PRESENTED WITH A THORNY SCIENTIFIC ISSUE TO TRY TO  
15 GET SOME RESOLUTION ABOUT THAT, THAT ISSUE.

16 AND OPTION C IS A VARIATION ON THAT. AND  
17 I THINK AT LEAST HERE WE'VE BEEN WORKING OFF OPTION  
18 B.

19 ANY COMMENTS, ANY THOUGHTS FROM ANYONE?  
20 IT WOULD BE GREAT IF WE COULD --

21 CHAIRMAN KLEIN: IS OS STEWARD ON, JEFF?

22 CHAIRMAN SHEEHY: NOT YET.

23 CHAIRMAN KLEIN: OKAY. I WOULD JUST  
24 COMMENT THAT GIVEN THE VARIOUS OPTIONS, I HAD A  
25 CHANCE TO TALK TO YOU, JEFF, AND TO TALK TO THE

## BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC STAFF. AND WE WERE ABLE TO HAVE A  
2 DISCUSSION OF THE VARIOUS ISSUES THAT AFFECTED THE  
3 EXTRAORDINARY PETITION PROCESS. AND SO SOME TIME  
4 HAS BEEN PUT INTO SOME VERY THOUGHTFUL DISCUSSIONS  
5 AND PUT INTO THE OPTION THAT IS NOW LABELED -- WHAT  
6 IS OUR CURRENT LABEL? -- OPTION B. AND THERE WAS  
7 SOME VERY IMPORTANT DISCUSSIONS THAT I HAD WITH IAN  
8 SWEEDLER ABOUT THE PROBLEMS WITH HAVING AN  
9 APPLICATION WHICH IS FILLED WITH PROPRIETARY  
10 INFORMATION AND WORKING -- IT'S A HUGE DISINCENTIVE  
11 TO PRIOR COMPANY OR A NONPROFIT SPONSOR TO HAVE TO  
12 GO THROUGH AND NEGOTIATE LINE BY LINE ON LONG  
13 APPLICATIONS OF WHAT'S PROPRIETARY AND (BREAKUP IN  
14 TRANSMISSION).

15 IT IS A DISINCENTIVE FOR THEM TO PUT THEIR  
16 BRILLIANT THOUGHTS AND THEIR LIFE'S WORK INTO AN  
17 APPLICATION TO US. SO I WOULD HOPE MAYBE WE COULD  
18 START WITH OPTION B, BUT I WANT -- I WOULD WANT TO  
19 HEAR FROM OS IF HE WANTED TO START WITH OPTION A.  
20 BUT I DO THINK THAT OPTION B DOES NOT HAVE A LOT OF  
21 THE LEGAL PROBLEMS AND DISINCENTIVES FOR SCIENTISTS  
22 IN THE SYSTEM WHETHER FROM PUBLIC OR PRIVATE SOURCES  
23 THAT OPTION A HAS.

24 MR. HARRISON: COULD I JUST ADD ONE  
25 ADDITIONAL COMMENT ABOUT OPTION A?

**BARRISTERS' REPORTING SERVICE**

1 CHAIRMAN KLEIN: WHO JUST JOINED?

2 CHAIRMAN SHEEHY: GO AHEAD, JAMES.

3 MS. SAMUELSON: JEFF, JOAN HERE.

4 MR. HARRISON: THE ISSUE YOU HIGHLIGHTED  
5 IS AN IMPORTANT ONE. AND IAN, I KNOW, CAN CONFIRM.  
6 OFTENTIMES WHEN WE GET A PUBLIC RECORDS ACT REQUEST,  
7 IT WILL TAKE WEEKS, IF NOT A MONTH, TO GO THROUGH  
8 THE PROCESS OF IDENTIFYING AND FIGURING OUT WHAT IS  
9 PROPRIETARY INFORMATION AND WHAT CAN BE PRODUCED  
10 PUBLICLY.

11 ONE OF THE CHALLENGES POSED BY OPTION A IS  
12 THAT GIVEN THE VERY LIMITED AMOUNT OF TIME FROM THE  
13 TIME AN EXTRAORDINARY PETITION IS -- FROM THE TIME  
14 THE APPLICANT RECEIVES ITS REVIEWS TILL BOARD  
15 REVIEW, IT WOULD BE VERY DIFFICULT TO CONCLUDE THOSE  
16 DISCUSSIONS OVER WHAT CAN BE REDACTED BEFORE THE  
17 EXTRAORDINARY PETITION WOULD HAVE TO BE FILED IN  
18 ADVANCE OF THE BOARD MEETING. SO IT'S JUST A  
19 PRACTICAL PROBLEM THAT WOULD BE POSED.

20 CHAIRMAN SHEEHY: AND, JOAN, WHERE WE ARE,  
21 WE'RE ON ITEM 3, CONSIDERATION OF CHANGES TO THE  
22 EXTRAORDINARY PETITION APPEALS PROCESS.

23 MS. SAMUELSON: OKAY.

24 CHAIRMAN SHEEHY: AND WE DID A LITTLE BIT  
25 OF DISCUSSION OF OPTION A. I ACTUALLY THINK THAT

**BARRISTERS' REPORTING SERVICE**

1 OPTION B IS WHAT'S OPERATIVE. JAMES, WOULD YOU MIND  
2 RUNNING THROUGH THE HIGH POINTS OF OPTION B, AND  
3 PERHAPS WE CAN GET A MOTION TO CONSIDER IT. AND  
4 EVEN IF WE DON'T HAVE A QUORUM, WE CAN DO A SENSE OF  
5 THE COMMITTEE.

6 MR. HARRISON: FIRST OF ALL, I SHOULD MAKE  
7 CLEAR THAT ALTHOUGH OPTION B HAS A HEADER THAT  
8 SPECIFIES EXTRAORDINARY PETITION PROCESS, AND  
9 ALTHOUGH THE DISCUSSION OF THIS PROPOSED POLICY  
10 AROSE OUT OF CONCERNS CONCERNING THE EXTRAORDINARY  
11 PETITION PROCESS, OPTION B IS NOT LIMITED TO  
12 CIRCUMSTANCES IN WHICH AN EXTRAORDINARY PETITION IS  
13 FILED. I JUST WANTED TO MAKE SURE THAT IS CLEAR AT  
14 THE OUTSET.

15 OPTION B GIVES THE BOARD A TOOL TO USE IN  
16 CIRCUMSTANCES WHEN AN APPLICATION IS PRESENTED AND  
17 AN ISSUE OF FACTUAL DISPUTE OR A FACTUAL QUESTION  
18 ARISES AT THE BOARD THAT CAN'T BE RESOLVED DURING  
19 THE BOARD MEETING ITSELF. AND UNDER THOSE VERY  
20 LIMITED CIRCUMSTANCES, OPTION B WOULD GIVE THE BOARD  
21 THE AUTHORITY TO CONDITIONALLY DENY THE APPLICATION  
22 TO GIVE THE BOARD TIME TO OBTAIN THE ADDITIONAL  
23 INFORMATION THAT IT NEEDS TO RESOLVE THE FACTUAL  
24 ISSUE.

25 THIS WOULDN'T BE INTENDED TO BE USED FOR

## BARRISTERS' REPORTING SERVICE

1 PROGRAMMATIC QUESTIONS. THE INTENT WOULD BE TO  
2 LIMIT THIS TO ISSUES OF SCIENTIFIC FACT THAT ARISE  
3 DURING THE REVIEW OF AN APPLICATION. OPTION B  
4 CREATES A BIFURCATED PROCESS. IF THE FACTUAL ISSUE  
5 THAT IS IDENTIFIED BY THE BOARD IS A FAIRLY  
6 STRAIGHTFORWARD ONE THAT CAN BE ANSWERED THROUGH  
7 RESEARCH BY STAFF OR BY THE ADMINISTRATIVE CHAIR OF  
8 THE WORKING GROUP OR THE ACTING CHAIR, THEN THE  
9 ISSUE WOULD BE REFERRED TO THE ADMINISTRATIVE CHAIR  
10 AND THE ACTING CHAIR OF THE GROUP, WHO WOULD EITHER  
11 CONDUCT THE RESEARCH THEMSELVES OR ASK STAFF TO DO  
12 IT AND WHO WOULD THEN REACH -- DISCUSS THE MATTER  
13 AND DETERMINE WHETHER OR NOT IN THEIR VIEW THE NEW  
14 INFORMATION WARRANTS RECONSIDERATION OF THE BOARD'S  
15 DECISION TO CONDITIONALLY DENY FUNDING FOR THE  
16 APPLICATION.

17 AND THAT DETERMINATION, IF THEY CONCUR,  
18 WOULD THEN GO TO THE BOARD FOR ITS REVIEW.

19 MS. BAUM: CAN I HAVE TWO POINTS OF  
20 CLARIFICATION? JUST SO WHEN WE'RE READING BACK,  
21 WHAT WE'RE CONSIDERING TO BE OPTION B ISN'T MARKED  
22 AS OPTION B. SO IT HAS A HEADING THAT'S CALLED  
23 "EXTRAORDINARY PETITION PROCESS, ADDITIONAL ANALYSIS  
24 OPTION." THE TITLE DOES NOT SAY OPTION B. I DON'T  
25 WANT THERE TO BE ANY CONFUSION BECAUSE THE OTHER

## BARRISTERS' REPORTING SERVICE

1 DOCUMENTS HAVE OPTION A AND ANOTHER DOCUMENT IS  
2 LABELED OPTION C. SO FOR POINT OF CONFUSION, I  
3 THOUGHT THAT WAS IMPORTANT TO NOTE.

4 MS. KING: IT DOES SAY ITEM 3 B AT THE TOP  
5 JUST SO PEOPLE KNOW WHAT THEY'RE LOOKING AT.

6 MS. BAUM: I WAS CONFUSED INITIALLY, SO I  
7 THOUGHT OTHERS MIGHT BE.

8 AND IT SEEMS TO ME THAT MAYBE THE TERM  
9 "STAFF" WOULD REFER TO THE PRESIDENT AND STAFF,  
10 POINTS OF CLARIFICATION.

11 MR. TORRES: WHERE DO YOU WANT THAT  
12 AMENDMENT?

13 MS. BAUM: I DON'T THINK THERE'S AN  
14 AMENDMENT. IT'S JUST I THOUGHT THAT IT SAID THAT IF  
15 THERE'S A POINT THAT NEEDS TO BE FURTHER  
16 INVESTIGATED, IT COULD BE REFERRED TO STAFF, BUT I  
17 THINK IMPLICIT IN THAT, MY UNDERSTANDING IT WAS THE  
18 PRESIDENT.

19 MS. KING: AS THE HEAD OF THE STAFF.

20 MR. TORRES: THAT'S NOT A HARD THING TO  
21 DO.

22 CHAIRMAN KLEIN: I'D JUST LIKE TO MAKE IT  
23 CLEAR THAT WHILE I WORKED ON THIS WITH YOU, JEFF,  
24 AND WITH THE STAFF, THAT THIS IS REALLY A CONCEPT  
25 THAT YOU CAME UP WITH TO TRY AND ADDRESS KIND OF AN

**BARRISTERS' REPORTING SERVICE**

1 INCOMPLETE PROCESS WE HAD. AND SO IT'S MY PRIVILEGE  
2 TO BE IN A SUPPORTING ROLE HERE.

3 CHAIRMAN SHEEHY: THANK YOU. I ACTUALLY  
4 WAS HOPING, UNLESS SOMETHING WAS REALLY PERTINENT,  
5 THAT JAMES COULD FINISH WITH HIS EXPLA -- WERE YOU  
6 DONE, JAMES?

7 MR. HARRISON: NO.

8 CHAIRMAN SHEEHY: IT'S KIND OF HARD FOR ME  
9 TO CHAIR A MEETING IF THERE'S NOT SOME PROCESS  
10 WHEREBY I'M ALLOWED TO CONDUCT IT. GO AHEAD, JAMES.

11 MR. HARRISON: JUST TO FINISH THEN, AS I  
12 WAS SAYING, THIS PROPOSAL INCLUDES A BIFURCATED  
13 OPTION. IF IT'S A SIMPLE, STRAIGHTFORWARD MATTER  
14 THAT CAN BE RESOLVED THROUGH INVESTIGATION SUCH AS  
15 RESOURCE PUBMED OR SOME OTHER EASILY ATTAINABLE  
16 INFORMATION, THEN IT WOULD BE THE ROLE OF THE  
17 ADMINISTRATIVE CHAIR AND THE ACTING CHAIR, IF THEY  
18 CONCUR, TO DETERMINE WHETHER OR NOT IN THEIR VIEW  
19 THE NEW INFORMATION MERITS RECONSIDERATION OF THE  
20 BOARD'S DETERMINATION CONDITIONALLY NOT TO FUND THE  
21 APPLICATION. IF THEY CONCUR, THEN THAT  
22 RECOMMENDATION WOULD GO TO THE BOARD FOR ITS  
23 CONSIDERATION.

24 IF THEY DON'T CONCUR OR IF IT'S A MATTER  
25 THAT REQUIRES SOME ADDITIONAL ANALYSIS, THE ACTING

## BARRISTERS' REPORTING SERVICE

1 CHAIR AND THE ADMINISTRATIVE CHAIR WOULD EACH  
2 DESIGNATE A MEMBER OF THE GRANTS WORKING GROUP, NOT  
3 INCLUDING THE MEMBERS WHO PARTICIPATED IN THE  
4 INITIAL REVIEW, AND THOSE FOUR SCIENTISTS WOULD  
5 REVIEW THE ISSUE WITH STAFF SUPPORT, IF NECESSARY,  
6 AND THEN WOULD MEET ALONG WITH THE TWO VICE CHAIRS  
7 OF THE GRANTS WORKING GROUP, THE BOARD CHAIR, AND  
8 ANOTHER PATIENT ADVOCATE TO CONSIDER THE SCIENTISTS'  
9 REVIEW OF THE INFORMATION AND ULTIMATELY TO CONSIDER  
10 A MOTION AS TO WHETHER OR NOT THE NEW INFORMATION OR  
11 ANALYSIS PRESENTED IN THEIR VIEW WARRANTS  
12 RECONSIDERATION OF THE BOARD'S CONDITIONAL  
13 DETERMINATION NOT TO FUND.

14 THAT RECOMMENDATION TOGETHER WITH ANY  
15 MINORITY REPORT WOULD THEN GO TO THE BOARD FOR ITS  
16 CONSIDERATION. IN ANY CASE THESE RECOMMENDATIONS  
17 WOULD BE PLACED ON THE BOARD'S CONSENT CALENDAR AND  
18 WOULD BE DISPOSED OF THAT WAY UNLESS A MEMBER OF THE  
19 BOARD ASKED FOR THE MATTER TO BE CONSIDERED AS A  
20 STANDALONE ITEM ON THE BOARD'S AGENDA.

21 CHAIRMAN SHEEHY: JUST TO BE CLEAR THAT  
22 THIS IS TAKING PLACE WITHIN THE CONSTRUCT OF THE  
23 GRANTS WORKING GROUP.

24 MR. HARRISON: THAT'S CORRECT. THIS WOULD  
25 BE A SUBGROUP OF THE GRANTS WORKING GROUP.

## BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: AND TO BE CLEAR, THIS  
2 IS -- THE MIDDLE ONE IS TITLED "ITEM 3 B, ADDITIONAL  
3 ANALYSIS OPTION." SO DO BOARD MEMBERS HAVE COMMENTS  
4 ON THIS?

5 MR. ROTH: CAN YOU HEAR ME OKAY?

6 CHAIRMAN SHEEHY: YES.

7 MR. ROTH: SO THERE ARE PARTS OF THIS I  
8 LIKE, BUT I WANT TO ASK A QUESTION AND SEE IF OTHERS  
9 HAVE THE SAME CONCERN. I WOULD THINK IF THIS  
10 DOESN'T REQUIRE AN EXTRAORDINARY PETITION, THAT WE  
11 WOULD EXPECT TO SEE A LOT OF SCIENTISTS WHO WERE  
12 DENIED APPROVAL STAND IN FRONT OF US AND MAKE A  
13 SCIENTIFIC CASE ON THE SPOT THAT WOULD BE HARD TO  
14 REFUTE AT THAT TIME AND, THEREFORE, REALLY CONSUME A  
15 LOT OF OUR TIME BY COMING BECAUSE IF YOU DON'T HAVE  
16 TO PUT IT DOWN IN WRITING, YOU CAN JUST SHOW UP AND  
17 SAY I WANT TO SHOW YOU WHERE THEY MADE THEIR  
18 MISTAKE, AND WE GET INTO A SCIENTIFIC DISCUSSION.

19 THEN IT REALLY, I THINK, INVITES THAT KIND  
20 OF VERY DIFFICULT SITUATION WE'VE HAD IN THE PAST  
21 WHERE WE JUST AREN'T EQUIPPED TO DO IT. BUT THE  
22 ATTEMPT TO GET TO THAT IS THE PART I LIKE ABOUT THIS  
23 PROPOSAL. THE PROBLEM I SEE IS THAT WITHOUT HAVING  
24 TO PUT SOMETHING IN WRITING TO BE CONSIDERED IN  
25 ADVANCE, WE'RE KIND OF HAVING TO REACT ON THE SPOT

## BARRISTERS' REPORTING SERVICE

1 IN A BOARD MEETING.

2 CHAIRMAN SHEEHY: WELL, WE TALKED ABOUT  
3 THIS IN PREPARING THIS. AND ONE OF THE DIFFICULTIES  
4 WE FACED WAS THAT IF YOU DO REQUIRE AN EXTRAORDINARY  
5 PETITION TO DO THIS, THEN YOU'VE BASICALLY INVITED  
6 EVERYONE TO SUBMIT AN EXTRAORDINARY PETITION BECAUSE  
7 THAT'S THE ONLY WAY THEY MIGHT HAVE AN OPPORTUNITY  
8 TO ENTER THIS PROCESS.

9 AND I THINK THE RECORD -- GIL IS NOT HERE,  
10 BUT I THINK THE RECORD IS PRETTY MIXED -- MAYBE PAT  
11 CAN SPEAK TO THAT -- WITH PEOPLE WHO ARE RIGHT UNDER  
12 THE SCORING, RIGHT BELOW THE FUNDABLE RANGE THAT  
13 SOME PERCENTAGE DO FILE EXTRAORDINARY PETITIONS, BUT  
14 IT'S NOT NECESSARILY ROUTINE. AND THAT IN THE  
15 CONTEXT OF DISCUSSING ONE OF THOSE GRANTS THAT A  
16 BOARD MEETING MAY MOVE UP FOR PROGRAMMATIC REASONS,  
17 A DISEASE THAT IMPACTS THEM, FOR INSTANCE, THERE IS  
18 A SCIENTIFIC ISSUE THAT WE CAN'T RESOLVE, IT WOULD  
19 BE HELPFUL TO BE ABLE TO GET A LITTLE BIT MORE  
20 INSIGHT TO IT EVEN IF THE APPLICANT HAD NOT DECIDED  
21 TO FILE AN EXTRAORDINARY PETITION.

22 DR. STEWARD: I'M SORRY TO BE LATE IN  
23 JOINING YOU. JUST WANTED TO LET YOU KNOW I'M HERE.

24 DR. LEVIN: JACOB LEVIN FROM UC IRVINE  
25 ALSO JOINED A FEW MINUTES AGO.

## BARRISTERS' REPORTING SERVICE

1 MS. KING: FOR THE RECORD, WE DO HAVE A  
2 QUORUM NOW, MR. SHEEHY. GO AHEAD, DR. OLSON.

3 DR. OLSON: SO I WAS JUST GOING TO RESPOND  
4 TO MR. SHEEHY'S QUESTION REGARDING THE EXTRAORDINARY  
5 PETITION. I THINK IT'S BECOMING A LITTLE BIT  
6 MORE -- IT'S BECOMING MORE COMMON FOR PEOPLE TO FILE  
7 IT. IT OBVIOUSLY REFLECTS THE BOARD'S WILLINGNESS  
8 TO IMPLEMENT IT AND TO RESPOND TO IT. I THINK THE  
9 BOARD, I THINK, HAS BEEN -- THE BOARD HAS BEEN VERY  
10 GOOD ABOUT DETERMINING WHETHER OR NOT THE  
11 EXTRAORDINARY PETITION HAS MERIT OR NOT. I DON'T  
12 KNOW THAT WE -- THAT THIS WOULD INCREASE OR DECREASE  
13 THE FREQUENCY OF FILING OF THOSE PETITIONS.

14 CHAIRMAN SHEEHY: BOB.

15 CHAIRMAN KLEIN: SO, JEFF, I THINK THIS  
16 WAS ACTUALLY A SUGGESTION BY STAFF, BY DR. SAMBRANO,  
17 THAT BY NOT LIMITING IT TO EXTRAORDINARY PETITIONS,  
18 IT WOULD SERVE TO DISSUADE PEOPLE FROM FILING AN  
19 EXTRAORDINARY PETITION. AND I THINK, JEFF, WHAT  
20 YOU'VE SAID IN DISCUSSIONS, THIS IS AN OPTION FOR  
21 THE BOARD. THIS IS NOT AN OPTION FOR THE CANDIDATE  
22 OR APPLICANT. AND SO THIS IS INTENDED REALLY FOR AN  
23 EXCEPTION.

24 THE TEXT TRIES TO STRESS THAT IT'S  
25 INTENDED THAT THE BOARD RESOLVE EVERYTHING IT

## BARRISTERS' REPORTING SERVICE

1 POSSIBLY CAN AT THE BOARD MEETING. THIS IS ONLY  
2 WHEN THE BOARD CANNOT RESOLVE IT AT THE BOARD  
3 MEETING, AND THIS IS NOT AN OPTION FOR AN APPLICANT  
4 TO REQUEST SOMETHING LIKE THIS. THIS IS TO BE A  
5 REAL EXCEPTION PROCESS WHEN SOMEONE ON THE BOARD  
6 FEELS THAT THIS IS SOMETHING WE SHOULD INVESTIGATE  
7 AND REQUIRES WORK BEYOND WHAT WE GET IN OUR  
8 SCIENTIFIC BRIEFING AT THE BOARD MEETING.

9 SO, DUANE --

10 MR. ROTH: JUST TO BE CLEAR, I UNDERSTAND  
11 THAT, BUT I DON'T UNDERSTAND WHAT PREVENTS SOMEONE  
12 FROM COMING IN THE OPEN SESSION AND MAKING THE  
13 COMMENTS THAT THEY HAVE IN THE PAST AND WHY THAT  
14 WOULDN'T BE ROUTINE. IF I HAD THIS POLICY RIGHT  
15 NOW, I WOULD TRY TO COME IN FRONT OF YOU AND IN  
16 THREE MINUTES CREATE DOUBT ABOUT A SCIENTIFIC ISSUE.

17 CHAIRMAN KLEIN: SO IN OUR PROCESS AT THE  
18 BOARD, WHEN WE'RE CONSIDERING APPLICATIONS, IF  
19 SOMEONE HAS FILED AN EXTRAORDINARY PETITION, THEY  
20 HAVE THE RIGHT TO BE HEARD ON THE EXTRAORDINARY  
21 PETITION. BUT IN THIS CASE, IF THEY'RE COMING  
22 BEFORE THE BOARD AND THIS IS NOT AN ISSUE THAT A  
23 BOARD MEMBER HAS RAISED OR THE STAFF HAS RAISED,  
24 THEY'RE GOING TO BE IN A POSITION WHERE THE BOARD  
25 WOULD NOT BE, FROM WHAT I COULD UNDERSTAND, NOT VERY

## BARRISTERS' REPORTING SERVICE

1 RECEPTIVE BECAUSE THEY HAVEN'T USED THE PROCESS THAT  
2 THE BOARD HAS SET OUT FOR THEM TO USE AS AN  
3 EXTRAORDINARY APPEAL.

4 SO IF THEY'RE JUST MAKING AN OFF-THE-HAND  
5 COMMENT, IT'S GOING TO BE VERY DIFFICULT FOR THE  
6 BOARD TO FOLLOW THAT KIND OF A COMMENT, AND IT WOULD  
7 HAVE TO BE A PRETTY UNUSUAL SITUATION. BUT AGAIN,  
8 THIS IS A SUGGESTION THAT DR. SAMBRANO HAD. HE  
9 THOUGHT THIS WOULD DISSUADE PEOPLE FROM  
10 UNNECESSARILY FILING EXTRAORDINARY PETITIONS. IT'S  
11 MY EXPECTATION THAT MEANS SOMEONE -- THIS MIGHT BE A  
12 SITUATION WHERE AN UNEXPECTED PROBLEM COMES UP AT  
13 THE BOARD MEETING THAT HAS NOT BEEN OTHERWISE  
14 PREVIOUSLY COVERED AND IS NOT PART OF THE GRANT  
15 REVIEW PROCESS.

16 CHAIRMAN SHEEHY: IF I MIGHT ADD, WE  
17 ALREADY HAVE PEOPLE WHO ARE SHOWING UP AND APPEALING  
18 TO US. I ACTUALLY THINK THAT IF GRANTEES ARE  
19 ANALYZING THE PROCESS, THEY HAVE A MUCH HIGHER  
20 CHANCE OF SUCCESS IF THEY IDENTIFY THEIR ISSUES IN  
21 ADVANCE OF FILING AN EXTRAORDINARY PETITION. I DO  
22 THINK WE NEED TO PUT THIS IN THE CONTEXT OF CHANGES  
23 THAT HAVE ALREADY BEEN IMPLEMENTED, WHICH IS THAT  
24 STAFF IS NOT ROUTINELY ANALYZING EXTRAORDINARY  
25 PETITIONS. THEY'RE ONLY GIVING US FEEDBACK ON THOSE

**BARRISTERS' REPORTING SERVICE**

1 ON WHICH THEY THINK THEY HAVE SOME MERIT.

2 DR. OLSON.

3 DR. OLSON: ACTUALLY THAT'S NOT CORRECT.  
4 WHEN THEY'RE FILED WITHIN ADEQUATE TIME, STAFF DOES  
5 LOOK AT ALL OF THEM. AND SO, IN FACT, YEAH.

6 MR. SWEEDLER: I THINK ACTUALLY THAT HAD  
7 BEEN THE PRACTICE. I THINK THE BOARD RECENTLY  
8 REQUESTED THAT STAFF NOT PROVIDE ANY SUBSTANTIVE  
9 COMMENTS UNLESS --

10 CHAIRMAN SHEEHY: FELT THAT THERE WAS SOME  
11 VALUE IN ORDER TO -- OBVIOUSLY WE WANT TO -- WE  
12 APPRECIATE AND NEED STAFF REVIEW. BUT UNLESS -- TO  
13 SAVE STAFF THE BURDEN OF HAVING TO EXHAUSTIVELY  
14 REPLY TO EACH THING, THEY FOUND NO MERIT IN IT, AND  
15 ALSO THE BOARD IS NOT TAKING UP EXTRAORDINARY  
16 PETITIONS UNLESS A MEMBER OF THE BOARD HAS AN  
17 INTEREST IN THE EXTRAORDINARY -- HAS FOUND SOME  
18 MERIT IN IT.

19 I DON'T KNOW. WE COULD POSSIBLY SEE A  
20 LINE OF SCIENTISTS TO ARGUE THEIR CASE, BUT  
21 HISTORICALLY YOUR BEST BET IS AT THE BOARD WHEN YOUR  
22 GRANT IS FIRST PRESENTED. ONCE YOU TAKE THE  
23 SCIENTIST OUT OF THE ROOM, THE ACTUAL FACTS OF THE  
24 CASE, WHETHER IT WAS BROUGHT UP IN EXTRAORDINARY  
25 PETITION OR BY SOMEONE AT A BOARD MEETING, IT'S

## BARRISTERS' REPORTING SERVICE

1 GOING TO BE THE FACTS. AND WE'RE GOING TO START  
2 WORKING THROUGH THE SCIENCE OTHERWISE.

3 I THINK GOING BACK TO THE ADMINISTRATIVE  
4 AND THE ACTING CHAIR OF THAT SESSION, THAT THEY'RE  
5 GOING TO TAKE A FAIRLY HARD LOOK AT IT. AND IF  
6 THERE REALLY IS SOMETHING THERE THAT NEEDS TO BE  
7 DISCOVERED, THEN WE HAVE THIS LARGER PROCESS TO  
8 REALLY LOOK INTO THE SCIENTIFIC ISSUE.

9 BUT I DON'T -- WE ALREADY HAVE PEOPLE  
10 COMING IN AND SENDING EXTRAORDINARY PETITIONS. I  
11 THINK THIS MIGHT END UP BEING A PROCESS THAT MIGHT  
12 REDUCE SOME OF THAT AS OPPOSED TO LEADING TO A  
13 LARGER SET OF EXTRAORDINARY PETITIONS AND  
14 PETITIONERS COMING TO THE BOARD.

15 I'D BE HAPPY TO HEAR OTHER COMMENTS.

16 MR. ROTH: I'D JUST LIKE TO FINISH BY  
17 ASKING WHAT IS THE PROCESS IF YOU DON'T FILE AN  
18 EXTRAORDINARY PETITION TO ASK FOR THIS REREVIEW?  
19 JUST THE BOARD?

20 CHAIRMAN SHEEHY: IT'S SOLELY AT THE  
21 DISCRETION OF THE BOARD. SO EVEN IF YOU FILE AN  
22 EXTRAORDINARY PETITION, YOU DON'T ACCESS THIS. EVEN  
23 IF YOU COME BEFORE THE BOARD AND MAKE PUBLIC COMMENT  
24 IN SUPPORT OF AN APPLICATION, YOU DON'T ACCESS THIS.  
25 THIS IS AN ACTION BY THE BOARD IF -- WE'VE SEEN SOME

## BARRISTERS' REPORTING SERVICE

1 OF THESE CASES WHERE WE HAVE A SUBSTANTIAL  
2 PERCENTAGE OF THE BOARD THAT FEELS COMFORTABLE WITH  
3 APPROVING AN APPLICATION, A SUBSTANTIAL PROPORTION  
4 OF THE BOARD THAT DOESN'T FEEL COMFORTABLE, THERE'S  
5 A SCIENTIFIC ISSUE, OR AN EMOTIONAL CONTEXT TO THE  
6 CASE, TO THE ISSUE, TO THE APPLICATION, AND THE  
7 BOARD SPENDS A LOT OF TIME KIND OF FLUMMOXED BY  
8 THIS.

9 IN THOSE INSTANCES, WE WOULD JUST DO THIS  
10 REFERRAL, AND I THINK THAT'S SOMETHING THAT THE  
11 BOARD CAN GET CONSENSUS ON FAIRLY QUICKLY, AND I  
12 THINK WE WOULD HAVE A HIGH COMFORT LEVEL THAT THE  
13 SCIENCE WAS THE ISSUE BEING ADDRESSED BY THIS. DOES  
14 THAT KIND OF MAKE SENSE?

15 ARE THERE OTHER COMMENTS, THOUGHTS?

16 DR. SLADEK: THIS IS JOHN SLADEK. ON  
17 BEHALF OF THE GRANTS WORKING GROUP THEN, IS THERE  
18 ANY PROVISION, IF WE TAKE THE SECOND BRANCH FROM  
19 JAMES HARRISON'S BIFURCATION, WHERE WE APPOINT  
20 ADDITIONAL MEMBERS OF THE GRANTS WORKING GROUP TO  
21 REVIEW MATTERS, IS THERE ANY CONSIDERATION THEN --  
22 ARE WE RECONSIDERING THE GRANT OR ONLY THE ISSUES  
23 FOR WHICH THERE ARE QUESTIONS BEING RAISED?

24 CHAIRMAN SHEEHY: ONLY THE ISSUES FOR  
25 WHICH THE QUESTION IS BEING RAISED.

## BARRISTERS' REPORTING SERVICE

1 DR. SLADEK: OKAY. THAT'S FAIRLY  
2 STRAIGHTFORWARD TO DO THEN. I THINK WE WOULD BE  
3 HAPPY TO HELP AND TAKE WHATEVER PRESSURE WE CAN OFF  
4 THE BOARD WHO HAS SO MANY ISSUES TO DEAL WITH.

5 CHAIRMAN SHEEHY: JUST TO BE CLEAR, THERE  
6 IS THE OPTION IN HERE -- I DON'T KNOW IF JAMES  
7 MENTIONED IT -- TO BRING IN OUTSIDE SPECIALISTS IF  
8 THERE'S A PARTICULARLY FINE POINT OF SCIENCE THAT  
9 MAY NOT BE REPRESENTED ON THE WORKING GROUP. WHAT  
10 WE WANT TO DO IS GET IT RIGHT.

11 DR. SLADEK: THANKS.

12 DR. FONTANA: I JUST WANT TO KIND OF  
13 CLARIFY. I'VE READ THROUGH SEVERAL OF YOUR  
14 PROPOSALS AND WANT TO SUMMARIZE, AND CORRECT ME IF  
15 I'M WRONG. NOW WHAT YOU ARE GOING TO DO IN THE  
16 WORKING GROUP IS YOU'RE GOING TO SET PRIORITY BOTH  
17 ON SCIENTIFIC MERIT AND THEN ON PROGRAMMATIC  
18 DISTRIBUTION IN THE DISEASE TEAMS AND FEASIBILITY  
19 STUDIES; IS THAT CORRECT?

20 CHAIRMAN SHEEHY: THAT'S THE NEXT ITEM ON  
21 THE AGENDA.

22 DR. FONTANA: AFTER DOING THAT, SO YOU  
23 WILL TAKE AWAY SOME OF THE BURDEN WHEN IT'S  
24 PRESENTED TO THE BOARD WHEN THESE EXTRAORDINARY  
25 PETITIONS COME AND THE BOARD CHANGES ITS POSITION

**BARRISTERS' REPORTING SERVICE**

1       BASED ON PROGRAMMATIC REVIEW.

2                   CHAIRMAN SHEEHY:  I MEAN YOU'RE  
3       PRESUPPOSING ADOPTION OF THE PROGRAMMATIC SCORE.

4                   DR. FONTANA:  WHICH I THINK IS A GOOD  
5       IDEA.  THEN IF THERE'S FURTHER QUESTION BY THE  
6       GRANTEE FROM SCIENTIFIC MERIT, LIKE THE WORKING  
7       GROUP MADE A MISTAKE OR THEY THOUGHT THEY MADE A  
8       MISTAKE, AND THAT GOES TO THE STAFF.  AND THE STAFF  
9       REVIEWS IT RIGHT NOW, AND THEY EITHER AGREE OR THEY  
10      DON'T AGREE WITH THE GRANTEE.  AND THAT'S WHEN IT  
11      COMES TO THE BOARD.

12                   AND YOU'RE SUGGESTING NOW THAT IF WE CAN'T  
13      DECIDE AT THE BOARD LEVEL AT THAT MEETING, THAT YOU  
14      WILL SEND IT BACK TO THIS --

15                   CHAIRMAN SHEEHY:  ADMINISTRATIVE AND THE  
16      ACTING CHAIR OF THAT GRANTS WORKING GROUP SESSION  
17      WHERE THEY CAN ACCESS READILY AVAILABLE INFORMATION.  
18      AND IF THEY CAN COME TO A CONCLUSION THAT THE  
19      SCIENTIFIC ISSUE HAS NO MERIT, THEN THAT'S FAIRLY  
20      DISPOSITIVE.  IF IT'S MORE COMPLEX AND THERE'S NOT  
21      AGREEMENT BETWEEN THE ACTING CHAIR AND THE  
22      ADMINISTRATIVE CHAIR, THEN IT GOES INTO THE LARGER  
23      SUBGROUP OF THE GRANTS WORKING GROUP FOR A MORE  
24      FORMAL EVALUATION OF THE ISSUES AND A  
25      DECISION-MAKING PROCESS.

## BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: TO PROVIDE THE FULL LEGAL  
2 PROCESS, IN ANY EITHER CASE IT WILL COME BACK TO THE  
3 BOARD FOR A FINAL -- FOR THE REAL FINAL DECISION.

4 CHAIRMAN SHEEHY: RIGHT.

5 DR. FONTANA: I UNDERSTAND THAT. WHERE I  
6 FIND MYSELF PERSONALLY UNCOMFORTABLE IS WHEN I'M  
7 PRESENTED AT A BOARD MEETING WITH THIS EXTRAORDINARY  
8 PETITION AND I'M SUPPOSED TO MAKE A VOTE BASED UPON  
9 SCIENTIFIC REVIEW OR THE OPINION OF THE STAFF  
10 WITHOUT HAVING THE GRANT IN FRONT OF ME AND THEN  
11 QUESTIONING THE WORKING GROUP'S SCORING OF IT, I  
12 FIND IT VERY UNCOMFORTABLE. SO I'M CURIOUS HOW  
13 THAT -- I THINK SEVERAL BOARD MEMBERS FEEL THE SAME.  
14 HOW ARE YOU ADDRESSING THAT?

15 CHAIRMAN SHEEHY: WELL, I THINK THE BOARD  
16 IS ULTIMATELY THE DECISION MAKER, DR. FONTANA. AND  
17 THE OTHER ISSUE HERE IS THAT, AND I WANT TO THANK  
18 THE CHAIR FOR GETTING THE DISTRIBUTION OF THE  
19 SCORES, THE STANDARD DEVIATION. WHEN YOU HAVE HIGH  
20 STANDARD DEVIATION ON AN APPLICATION, YOU MAY END UP  
21 WITH A 65, BUT THE LOW END MAY BE 40 AND THE HIGH  
22 END MAY BE 85. SO THERE MAY ACTUALLY BE A REAL  
23 ISSUE OF SCIENCE THAT'S NOT RESOLVED BY THE WORKING  
24 GROUP. YOU HAD TWO DIFFERENT OPTICS ON THAT  
25 PARTICULAR ISSUE REPRESENTED AT THE WORKING GROUP,

## BARRISTERS' REPORTING SERVICE

1 AND YOU REALLY DON'T KNOW PRECISELY. THIS IS  
2 MORE -- THE PEER REVIEW PROCESS IS IN SOME WAYS AN  
3 ART FORM.

4 AND SO IF, ESPECIALLY IF THIS IS MISSION  
5 CRITICAL SCIENCE, IF THERE'S AN OPPORTUNITY TO TRY  
6 GET TO THE BOTTOM OF IT, SOMETIMES PEOPLE COME TO  
7 THE BOARD, WE HAD THE ABOODY CASE, THEY'RE ABLE TO  
8 PRESENT INFORMATION THAT CLEARLY SHOWS THAT THE  
9 APPLICANT DID HAVE -- WAS GOING DOWN THE RIGHT ROAD.  
10 WE'RE ABLE TO RESOLVE THAT AT THE BOARD LEVEL, BUT  
11 SOMETIMES WE MAY NOT BE ABLE TO RESOLVE IT AT THE  
12 BOARD LEVEL.

13 MR. TORRES: OR WANT TO.

14 CHAIRMAN SHEEHY: OR WANT TO ACTUALLY.  
15 THANK YOU, SENATOR TORRES. THIS GIVES US AN  
16 OPPORTUNITY NOT TO BE SITTING THERE SUDDENLY  
17 CONFRONTED WITH ALL THIS INFORMATION AND HAVING TO  
18 MAKE A DECISION.

19 DR. FONTANA: I WOULD JUST LIKE TO SEE THE  
20 PROCESS BEFORE IT EVEN CAME TO THE BOARD SO THAT AS  
21 BOARD MEMBERS, WE MAKE A COMFORTABLE DECISION.

22 MR. TORRES: JEANNIE, CAN YOU SPEAK UP A  
23 BIT? THANK YOU.

24 CHAIRMAN KLEIN: JEANNIE, THIS PROCESS  
25 THAT JEFF IS CREATING HERE, I THINK, CAN HELP

## BARRISTERS' REPORTING SERVICE

1 BECAUSE THE SCIENTIFIC STAFF AND THE REVIEWS WILL  
2 ALWAYS TRY AND FILL IN THOSE GAPS AND GIVE US AS  
3 MUCH INFORMATION. BUT IF THERE'S A GAP THAT REALLY  
4 IS NOT FILLED IN, INSTEAD OF US TRYING TO FIGURE IT  
5 OUT, WE CAN SEND IT BACK AND GET AN EXPERT OPINION  
6 AND THEN REACH A FINAL DECISION. SO THIS REALLY  
7 HELPS ADDRESS THE PROBLEM YOU'RE TALKING ABOUT.

8 CHAIRMAN SHEEHY: I THINK IF YOU LOOK  
9 AGAIN HISTORICALLY, WE'RE ONLY PROBABLY TALKING  
10 ABOUT (INTERFERENCE WITH THE TRANSMISSION) EVEN FOR  
11 DISCUSSION TERMS INTO THIS CATEGORY IN EVERY REVIEW.  
12 THAT'S NOT EVEN TO ASSUME THAT AUTOMATICALLY THOSE  
13 WOULD BE SENT THROUGH THIS PROCESS.

14 GENERALLY IT'S FAIRLY CLEAR THAT MOST  
15 GRANTS ARE FUNDABLE OR NOT FUNDABLE. AND A LOT OF  
16 EXTRAORDINARY PETITIONS THAT COME IN, I THINK  
17 THEY'RE FAIRLY STRAIGHTFORWARD IN WHETHER OR NOT  
18 PEOPLE WERE UNHAPPY WITH THEIR SCORES OR IN WHICH  
19 THEY IDENTIFIED A REAL ISSUE THAT WE CAN KIND OF --  
20 AND STAFF HAS BEEN ABLE TO PROVIDE INFORMATION THAT  
21 THERE WAS SOME MERIT TO THEIR DISPUTE OF THE SCORE.

22 DR. FONTANA: OKAY. THANK YOU.

23 MS. SAMUELSON: IT SEEMS TO ME THAT THE  
24 TIMES THAT THE EXTRAORDINARY PETITION HAS REALLY  
25 BEEN A BENEFIT HAS BEEN WHEN THE PROGRAMMATIC ISSUES

## BARRISTERS' REPORTING SERVICE

1 ARE KIND OF DEFINED AS SCIENTIFIC MERIT ISSUES AT  
2 THE BEGINNING. AND IT TAKES A WHILE, OR BY SOME  
3 FOLKS ANYWAY, AND IT TAKES A WHILE FOR US TO TEASE  
4 OUT THE FACT THAT THERE'S AN ISSUE THERE AND THAT  
5 IT'S DEBATABLE. AND IF THIS IS GOING TO FLESH THAT  
6 OUT BETTER, I THINK IT'S A GREAT THING. IF IT'S  
7 GOING TO DERAIL THAT HEALTHY SECOND LOOK, THEN I  
8 WOULDN'T BE SO CRAZY ABOUT IT.

9 AND SO I'M JUST TRYING TO FIGURE OUT WHICH  
10 IT IS BECAUSE I THINK THE DISCOMFORT SOMETIMES IS  
11 WHEN THE BOARD FEELS IT'S BEING ASKED TO VOTE  
12 AGAINST SCIENTIFIC MERIT, UNDERSTANDABLY. AND I  
13 THINK IT'S ONE OF THE KIND OF CENTRAL ISSUES FOR US  
14 IN WHAT PRIORITIES DO WE HAVE FOR OUR GRANT  
15 PORTFOLIO. AND IT'S KIND OF -- AND THAT IS KIND OF  
16 A WORK IN PROGRESS NOW, I THINK.

17 CHAIRMAN SHEEHY: WELL --

18 MS. SAMUELSON: AND AT TIMES I THINK THE  
19 EXTRAORDINARY PETITION PROCESS HAS BEEN VERY HELPFUL  
20 IN GIVING US A CHANCE TO TALK ABOUT THAT AT THE  
21 BOARD LEVEL.

22 CHAIRMAN SHEEHY: WE'RE NOT ELIMINATING  
23 THE EXTRAORDINARY PETITION.

24 MS. SAMUELSON: I KNOW. IT'S JUST --

25 CHAIRMAN SHEEHY: I THINK THIS IS HIGHLY

## BARRISTERS' REPORTING SERVICE

1 UNLIKELY TO HAVE AN IMPACT ON 68S AND 69S WHERE THE  
2 BOARD PROGRAMMATICALLY OR FOR OTHER REASONS IS  
3 WILLING TO MOVE STUFF UP. I THINK THAT THIS WILL  
4 HAVE A BIGGER IMPACT ON LOWER SCORES WHERE A REAL  
5 SCIENTIFIC ISSUE HAS BEEN IDENTIFIED. IT'S ANOTHER  
6 TOOL. AND I DON'T THINK ANYBODY -- ANY OF US HERE  
7 CAN PREDICT HOW THE BOARD WILL UTILIZE THIS TOOL.  
8 AND IT MAY BE -- I UNDERSTAND YOUR FEAR THAT THIS  
9 COULD TAKE SOME OF THE ENERGY OUT OF THE BOARD'S  
10 CONSIDERATION OF EXTRAORDINARY PETITIONS, BUT THAT'S  
11 KIND OF UP TO BOARD MEMBERS NOW ANYWAY AND REALLY IS  
12 ALMOST AN INDIVIDUAL QUESTION FOR EACH BOARD MEMBER  
13 HOW THEY APPROACH AN EXTRAORDINARY PETITION.

14 CHAIRMAN KLEIN: JOAN, THERE'S NO INTENT  
15 TO USE THIS AS A LIMITATION ON THE EXTRAORDINARY  
16 PETITION PROCESS. THAT'S A PROCESS THAT'S  
17 ESTABLISHED. IT GIVES OPPORTUNITY FOR PUBLIC  
18 REVIEW, PUBLIC DEBATE. IT'S A VERY IMPORTANT  
19 PROCESS OF RECOURSE.

20 SO THIS IS JUST A TOOL WHERE, YOU KNOW,  
21 THE BOARD MIGHT BE FACED WITH SAYING NO BECAUSE THEY  
22 CAN'T RESOLVE THIS ISSUE. AND THIS NEEDS TO BE  
23 TREATED AS A REAL EXCEPTION; BUT IF THERE'S A REAL  
24 SCIENTIFIC ISSUE THAT JUST HAS ESCAPED THE PROCESS  
25 AND ARISES LATE AND IT GIVES US AN ABILITY NOT TO

## BARRISTERS' REPORTING SERVICE

1 EITHER DEFAULT TO A NO OR, ON THE OTHER HAND,  
2 DEFAULT TO A YES WHEN WE REALLY DON'T KNOW THE  
3 ANSWER.

4 MS. SAMUELSON: YEAH.

5 MR. ROTH: JEFF.

6 DR. FRIEDMAN: IF I COULD OFFER A COUPLE  
7 OF THOUGHTS, PLEASE.

8 CHAIRMAN SHEEHY: SURE.

9 DR. FRIEDMAN: ONE IS THAT I THINK IT'S  
10 ADMIRABLE TO TRY AND FORMALIZE A PROCESS, WHICH AS  
11 VARIOUS OF YOU HAVE SAID, AND I SHARE THE DISCOMFORT  
12 WITH THE RIGOR WITH WHICH WE DO THIS, THERE'S A  
13 LEGITIMATE DESIRE ON OUR PART AS BOARD MEMBERS NOT  
14 TO HAVE MISPERCEPTIONS OR MISTAKES AFFECT IMPORTANT  
15 OUTCOMES. THERE'S ALSO A DESIRE ON THE PART OF THE  
16 SCIENTISTS TO PRESENT THEIR RESEARCH IN THE BEST  
17 POSSIBLE LIGHT AND OF THE PATIENT ADVOCATES AND  
18 THOSE AFFECTED BY DISEASES AND CONDITIONS TO MAKE  
19 SURE THAT THE PROPER ATTENTION IS PAID TO THEIR  
20 PARTICULAR NEEDS. WE'RE TRYING TO BALANCE ALL THESE  
21 THINGS AT ONE TIME.

22 I THINK THAT THIS PROPOSAL IS A VERY  
23 REASONABLE STEP TO TAKE, BUT I SHARE EVERYBODY'S  
24 CONCERN THAT WE DON'T KNOW EXACTLY HOW THIS IS GOING  
25 TO TURN OUT. AND RIGHT NOW WE'RE SAYING, OH, I

## BARRISTERS' REPORTING SERVICE

1 THINK IT'S ONLY GOING TO BE THIS WAY OR I THINK IT'S  
2 ONLY GOING TO BE THAT WAY.

3 IF I COULD MAKE A SUGGESTION PLEASE, IT  
4 WOULD BE TO SAY THAT WE TRY THIS FOR A FINITE  
5 PERIOD. IT CAN BE A YEAR, IT CAN BE 18 MONTHS, IT  
6 CAN BE TWO YEARS. I DON'T CARE. BUT THAT WE  
7 FORMALLY TEST IT DURING THAT TIME AND BRING IT BACK  
8 BECAUSE THERE MAY BE UNINTENDED CONSEQUENCES OF WHAT  
9 LOOKS LIKE A VERY REASONABLE THING THIS MORNING  
10 RATHER THAN TRYING TO MAKE THIS THE MOST PERFECT  
11 SYSTEM WHERE WE THOUGHT THROUGH EVERYTHING, WE'RE  
12 STILL GOING TO FORGET THINGS. I THINK WE HAVE TO  
13 TRY AND BRING MORE FORMALITY AND CLARITY TO THIS  
14 PROGRAM.

15 I REALLY APPRECIATE THE THINKING THAT OS  
16 AND THE STAFF AND OTHER PEOPLE HAVE BROUGHT TO THIS.  
17 AND I'M WILLING TO TEST SOMETHING, AND I WOULD ONLY  
18 ASK THAT WE PLEASE HAVE IT AS A FORMAL TRIAL PERIOD,  
19 BRING IT BACK FOR RECONSIDERATION AT A LATER TIME  
20 SHOULD IT PROVE TOO CUMBERSOME, TOO UNFAIR, TOO  
21 TIME-CONSUMING, WHATEVER. THANK YOU.

22 CHAIRMAN SHEEHY: I THINK THAT'S A GREAT  
23 IDEA. IN FACT, IF YOU WOULD LIKE TO SUGGEST A TIME  
24 FRAME, I WOULD BE COMFORTABLE WITH WHATEVER. I  
25 ALWAYS THINK IT'S IMPORTANT TO DO ANALYSIS OF THE

## BARRISTERS' REPORTING SERVICE

1 THINGS WE DO.

2 DR. FRIEDMAN: JEFF, THANK YOU. I DON'T  
3 KNOW WHAT THE RIGHT TIME IS. I THINK A YEAR MAY BE  
4 TOO SHORT BECAUSE WE DON'T HAVE THAT MANY CYCLES  
5 THAT GO THROUGH. I THINK TWO YEARS IS PROBABLY AS  
6 LONG AS I WOULD LIKE TO TRY IT. BUT HONESTLY, I  
7 DON'T CARE; AND IF OTHER PEOPLE ON THE BOARD HAVE  
8 STRONG OPINIONS, I PROBABLY AM GOING TO VOTE WITH  
9 YOU GUYS. THOSE ARE JUST MY THOUGHTS. THANK YOU.

10 CHAIRMAN SHEEHY: OKAY. WHEN IT COMES  
11 TIME TO MAKE AN AMENDMENT, WE'LL STIPULATE -- WHEN  
12 IT COMES TIME TO MAKE A MOTION, WE'LL STIMULATE A  
13 TIME PERIOD BY THE MAKER OF THE MOTION. AS I SAID,  
14 I'M COMFORTABLE WITH ANY TIME PERIOD.

15 ARE THERE OTHER COMMENTS BEFORE WE GO TO A  
16 MOTION? WOULD SOMEONE LIKE TO MAKE A MOTION?

17 CHAIRMAN KLEIN: I WILL MAKE A MOTION FOR  
18 APPROVAL. THIS IS BOB KLEIN.

19 CHAIRMAN SHEEHY: WITH THE TIME FRAME.

20 CHAIRMAN KLEIN: WITH THE TIME PERIOD OF,  
21 I THINK, 18 MONTHS WILL GO THROUGH A FULL CYCLE OF  
22 DIFFERENT KINDS OF GRANTS, AND WE'LL HAVE  
23 EXPERIENCE. AND OBVIOUSLY IF WE ARE EXPERIENCING ON  
24 AN EARLIER BASIS ISSUES, WE CAN AMEND IT.

25 DR. FRIEDMAN: I'M HAPPY TO SECOND THAT,

**BARRISTERS' REPORTING SERVICE**

1 BOB.

2 CHAIRMAN SHEEHY: OKAY. IS THERE FURTHER  
3 DISCUSSION? PUBLIC COMMENT? AND IF ANYONE AT ANY  
4 OF THE SITES HAS PUBLIC THERE THAT WANTS TO COMMENT,  
5 PLEASE LET ME KNOW. GO AHEAD. WE HAVE PUBLIC HERE  
6 IN SAN FRANCISCO TO COMMENT. BUT AFTER THE END OF  
7 THE SAN FRANCISCO PUBLIC COMMENT, PLEASE LET ME KNOW  
8 IF YOU HAVE A PUBLIC COMMENT AT YOUR SITE.

9 MS. SAMUELSON: THIS IS JOAN. I HAVE A  
10 QUESTION. I THINK I HEARD THAT THERE'S -- SORRY.  
11 I'VE FORGOTTEN THE NAME OF IT. NEVER MIND.

12 CHAIRMAN SHEEHY: OKAY.

13 MS. SAMUELSON: I KNOW. SORRY. CAN I  
14 HAVE THE FLOOR AGAIN? IT'S JOAN. THERE WAS ONE  
15 PIECE OF THIS, I GUESS, THAT COULD BE HANDLED IN THE  
16 CONSENT CALENDAR; IS THAT RIGHT? I'M RELUCTANT TO  
17 DO THAT.

18 CHAIRMAN SHEEHY: YEAH. THE CHAIR --

19 CHAIRMAN KLEIN: IF THE ADMINISTRATIVE  
20 CHAIR AND THE ACTING CHAIR SEND BACK A COMMUNICATION  
21 THAT THEY DON'T RECOMMEND ANY FURTHER ACTION AND  
22 THEY BOTH AGREE, THEN IT CAN GO ON THE CONSENT  
23 CALENDAR. BUT ANY BOARD MEMBER CAN PULL IT OFF THE  
24 CONSENT CALENDAR, JOAN. SO IT PROVIDES BOTH AN  
25 EFFICIENT WAY TO HANDLE IT, BUT IT ALLOWS THE BOARD

## BARRISTERS' REPORTING SERVICE

1       OVERSIGHT.  EVERY ONE OF THE 29 MEMBERS HAS THE  
2       RIGHT TO PULL IT OFF THE CONSENT CALENDAR, AND WE  
3       HAVE THE RIGHT TO DISCUSS IT.

4               MS. SAMUELSON:  AS AN ADDITIONAL  
5       PROTECTION, IT MIGHT BE GOOD TO -- I DON'T KNOW.  
6       MAYBE THIS IS LOADING UP WITH TOO MANY PROCEDURES.  
7       I KNOW I GO TO THE MEETINGS AND OFTEN THERE ARE  
8       SEVERAL ITEMS THAT I'M NOT PREPARED TO THINK ABOUT.  
9       I HAVEN'T REALIZED WERE ON THE AGENDA OR WE  
10      AGENDIZED THEM VERY LATE IN THE GAME.  SO THAT MAY  
11      BE -- WE MAY NOT BE ABLE TO MAKE USE OF THAT --

12              CHAIRMAN KLEIN:  OKAY.

13              MS. SAMUELSON:  -- READILY ENOUGH TO MAKE  
14      A DIFFERENCE.  DO YOU KNOW WHAT I'M SAYING?  IF WE  
15      DON'T KNOW WE NEED TO OBJECT BECAUSE --

16              CHAIRMAN KLEIN:  SO A PRACTICE AT THE  
17      BOARD, CERTAINLY WHILE WE'RE IN THIS PILOT PROGRAM,  
18      JOAN, WHAT I WOULD DO AS THE CHAIR IS ADOPT THE  
19      PRACTICE THAT JAMES CAN INSTITUTIONALIZE AND THE  
20      ATTORNEYS CAN MAKE A RECORD OF THAT JUST WHEN WE  
21      SEND OUT THE AGENDA, WE WILL NOTIFY THE BOARD AND  
22      THE PUBLIC IF THERE IS A CONSENT ITEM THAT DEALS  
23      WITH THIS PRACTICE.

24              MS. SAMUELSON:  GREAT.

25              MR. ROTH:  JEFF, CAN WE CALL THE QUESTION?

**BARRISTERS' REPORTING SERVICE**

1                   CHAIRMAN SHEEHY: WELL, WE HAVE PUBLIC  
2 COMMENT HERE. THAT'S THE LAST STEP.

3                   MR. REED: THIS IS DON REED. JAMES  
4 HARRISON USED THE WORD "MINORITY REPORT". AND I  
5 REMEMBER AT A PREVIOUS MEETING OF THIS COMMITTEE,  
6 THERE WAS DISCUSSION OR MAYBE AT THE ICOC MEETING,  
7 DISCUSSION OF THE MINORITY REPORT, AND SOMEBODY SAID  
8 IT WAS AUTOMATIC. ACTUALLY THERE WOULD BE A  
9 MINORITY REPORT. BUT I WONDER IF THERE SHOULDN'T BE  
10 SOMETHING IN THE FRAMEWORK WHICH SAYS -- EVERY  
11 QUESTION HAS TWO SIDES, BUT THERE WOULD BE AN  
12 AUTOMATIC INCLUSION OF A MINORITY REPORT AT THE  
13 PRESENCE OR ABSENCE OF EVIDENCE IN THERE THAT COULD  
14 HELP TO ELIMINATE REQUESTS THAT WERE NOT REASONABLE.  
15 JUST I LIKE TO HEAR BOTH SIDES. I LIKE THE IDEA  
16 THERE WOULD BE A ROUTINE INCLUSION OF A MINORITY  
17 REPORT AND ANY RATIONALITY THAT LED TO THAT.

18                   CHAIRMAN SHEEHY: MINORITY REPORT IS A  
19 TERM OF ART HERE, AND IT REPRESENTS WHEN THERE'S A  
20 DISPUTE AT THE GRANTS WORKING GROUP AND THE FINDING  
21 OF 35 PERCENT OF THOSE WHO WERE TAKING PART IN THE  
22 DECISION DON'T AGREE WITH THE MAJORITY. AND SO A  
23 MINORITY REPORT WOULD BE FILED IN THOSE  
24 CIRCUMSTANCES.

25                   AND THAT PROCESS, AS AT THE GRANTS WORKING

## BARRISTERS' REPORTING SERVICE

1 GROUP, IS INCLUDED HERE. SO THAT WHEN WE GO TO THE  
2 LARGER, SMALLER GROUP, THERE IS 35 PERCENT OF THOSE  
3 PEOPLE WHO TAKE PART IN THAT DECISION DON'T AGREE  
4 WITH THE ENTIRE GROUP'S DECISION, THAT GETS  
5 FORWARDED TO THE BOARD. SO THAT'S THE CONTEXT IN  
6 WHICH A MINORITY REPORT IS BEING USED HERE. BUT  
7 ALWAYS THERE'S BACK AND FORTH, THERE'S EXTRAORDINARY  
8 PETITIONS, THERE'S PEOPLE TAKING PRO AND CON,  
9 THERE'S A MATTER IN DISPUTE. WE'LL BE HEARING  
10 EVIDENCE FROM BOTH SIDES. THAT'S WHAT STIMULATES IT  
11 IS THAT THERE'S A LOT OF EVIDENCE FROM BOTH SIDES TO  
12 HAVING THIS DEBATE.

13 SO I THINK WE'RE READY TO CALL THE  
14 QUESTION UNLESS SOMEONE HAS PUBLIC COMMENT AT  
15 ANOTHER SITE. CAN WE HAVE A RESTATEMENT OF THE  
16 MOTION, PERHAPS JAMES.

17 MR. HARRISON: YES. THE MOTION IS TO  
18 RECOMMEND APPROVAL OF THE ADDITIONAL ANALYSIS  
19 OPTION, WHICH IS IDENTIFIED AS OPTION B, FOR A TRIAL  
20 PERIOD OF 18 MONTHS. AND UPON EXPIRATION OF THIS  
21 PERIOD OF TIME, THE POLICY WILL BE SUBJECT TO  
22 RECONSIDERATION BY THE BOARD.

23 CHAIRMAN SHEEHY: OKAY.

24 MS. KING: JACOB LEVIN.

25 DR. LEVIN: YES.

## BARRISTERS' REPORTING SERVICE

1 MS. KING: MARCY FEIT, HAVE YOU BEEN ABLE  
2 TO JOIN US YET? I KNOW YOU'RE PLANNING ON IT. NOT  
3 YET.

4 MICHAEL FRIEDMAN.

5 DR. FRIEDMAN: YES.

6 MS. KING: BOB KLEIN.

7 CHAIRMAN KLEIN: YES.

8 MS. KING: JEANNIE FONTANA.

9 DR. FONTANA: YES.

10 MS. KING: DUANE ROTH.

11 MR. ROTH: YES.

12 MS. KING: JOAN SAMUELSON.

13 MS. SAMUELSON: YES.

14 MS. KING: JEFF SHEEHY.

15 CHAIRMAN SHEEHY: YES.

16 MS. KING: OSWALD STEWARD.

17 DR. STEWARD: YES.

18 MS. KING: ART TORRES.

19 MR. TORRES: AYE.

20 MS. KING: AND FOR THE RECORD, THAT MOTION  
21 CARRIES.

22 CHAIRMAN SHEEHY: OKAY. BEFORE WE LEAVE  
23 THIS ITEM, I MEAN, OS, YOU WANT TO DISCUSS OPTION A  
24 OR ARE YOU COMFORTABLE WITH WHERE WE ARE RIGHT NOW?

25 DR. STEWARD: I'M FINE WITH WHERE WE ARE

## BARRISTERS' REPORTING SERVICE

1 RIGHT NOW.

2 CHAIRMAN SHEEHY: OKAY. THEN PERHAPS  
3 WOULD YOU MIND INTRODUCING, DR. STEWARD, THE NEXT  
4 ITEM BECAUSE I THINK THAT CAME FROM YOU,  
5 PROGRAMMATIC SCORING, ITEM 4.

6 DR. STEWARD: SURE. SO THIS CAME UP  
7 REALLY, I THINK, IN RESPONSE TO SEVERAL COMMENTS  
8 THAT HAVE BEEN MADE OVER MAYBE THE LAST SIX OR EIGHT  
9 MONTHS ABOUT MAYBE SOME OF THE REVIEWERS NOT FULLY  
10 UNDERSTANDING THE IMPORTANCE OF THE PROGRAMMATIC  
11 PART OF THE REVIEW PROCESS AND GIVING IT SHORT  
12 SHRIFT BECAUSE IT SORT OF CAME AT THE END AND  
13 PERHAPS THERE WERE PLANES TO CATCH AND SO FORTH.

14 AND I HAVE TO SAY I THOUGHT OF THIS, I  
15 THINK, AT THE LAST SCIENTIFIC MEETING AND REALLY WAS  
16 THINKING OUT LOUD AT THE TIME. BUT THE IDEA WAS  
17 SIMPLY TO MAKE THE PROCESS FORMAL IN THE SAME WAY  
18 THAT THE SCIENTIFIC REVIEW WAS DISCUSSED BY MEMBERS  
19 OF THE SCIENTIFIC REVIEW GROUP WITH THE PATIENT  
20 ADVOCATES PRESENT AND LISTENING. THE PROGRAMMATIC  
21 REVIEW WOULD BE DONE THE SAME WAY AND ACTUALLY  
22 SCORED, WHICH WOULD BE THE WAY THAT IT WOULD CLEARLY  
23 INDICATE THAT THE PROCESS WAS TRULY IMPORTANT.

24 THAT WOULD THEN FORM THE BASIS FOR THE  
25 DISCUSSION OF THE EVENTUAL ORDER OF THE PROPOSALS

## BARRISTERS' REPORTING SERVICE

1 AND DISCUSSIONS OF MOVING THINGS UP ON THE BASIS OF  
2 PROGRAMMATIC REVIEW WITH A CLEAR UNDERSTANDING OF  
3 WHERE THE DIFFERENT GRANTS ACTUALLY FELL WITH  
4 RESPECT TO THE ISSUE OF PROGRAMMATIC REVIEW, PROGRAM  
5 RELEVANCE, AND SO FORTH. AND THEN THE IDEA THAT  
6 BOTH OF THOSE SCORES WOULD END UP BEING REPORTED TO  
7 THE BOARD IN ADDITION TO THE ORDER EVENTUALLY  
8 REACHED BY THE COMBINED REVIEW GROUP. SO THAT WAS  
9 THE IDEA.

10 CHAIRMAN SHEEHY: OKAY. DO FOLKS WANT TO  
11 DISCUSS THIS?

12 CHAIRMAN KLEIN: SO CAN I ASK A QUESTION  
13 OF OS?

14 CHAIRMAN SHEEHY: SURE. BE MY GUEST.

15 CHAIRMAN KLEIN: SO, OS, EACH OF THE RFA'S  
16 IS DIFFERENT. SO THERE'S DIFFERENT PROGRAMMATIC  
17 ISSUES THAT WOULD ARISE IN EACH RFA. SO IT WOULD  
18 SEEM TO ME TO BE DIFFICULT TO ARRIVE AT THE SAME  
19 CRITERIA FOR SCORING BECAUSE OF THE GREAT  
20 DIFFERENCES. SO, FOR EXAMPLE, IN THE TRAINING  
21 PROGRAM OR IN THE BRIDGES PROGRAM, YOU KNOW,  
22 EXPANDING ACCESS TO THE EVERYONE IN THE STATE HAVING  
23 DIVERSITY MIGHT BE A CRITERIA, BUT THAT'S A NOT A  
24 CRITERIA IN EARLY TRANSLATION. SO WE'D HAVE TO FIND  
25 SOME WAY TO CREATE A WHOLE SET OF CRITERIA FOR EACH

## BARRISTERS' REPORTING SERVICE

1 RFA.

2 AND IN LISTENING TO 30 DIFFERENT PEER  
3 REVIEWS OVER THE LAST SIX YEARS, I'M ALWAYS  
4 MARVELLING AT THE INSIGHTS THAT THE DIFFERENT PEOPLE  
5 BRING UP DURING PROGRAMMATIC REVIEW, RAISING ISSUES  
6 THAT I HADN'T THOUGHT ABOUT AS BEING IMPORTANT. IF  
7 THOSE WEREN'T PART OF THE, IN QUOTE, FORMAL  
8 CRITERIA, THE ISSUE IS HOW DO YOU INCORPORATE THEM  
9 INTO THE SCORING PROCESS? SO I'M TRYING TO  
10 UNDERSTAND MECHANICALLY HOW WE WOULD CARRY THIS OFF.

11 DR. STEWARD: RIGHT. ACTUALLY IT'S A VERY  
12 INTERESTING QUESTION, BOB. I HADN'T REALLY THOUGHT  
13 ABOUT HAVING A SET OF PREDEFINED CRITERIA FOR  
14 PROGRAMMATIC REVIEW. I THINK YOU MAKE A VERY  
15 EXCELLENT POINT, THAT THE THINGS THAT BECOME  
16 RELEVANT FOR PROGRAMMATIC REVIEW, EVERYONE SORT OF  
17 HAS SOMETHING IN THEIR HEART OF HEARTS THAT  
18 REPRESENTS AN ELEMENT IN PROGRAMMATIC REVIEW. AS  
19 YOU SAID, PUTTING THOSE DOWN ON PAPER IS NOT ALWAYS  
20 EASY AND CERTAINLY NOT ALWAYS EASY TO PUT THEM DOWN  
21 IN ADVANCE. I THINK, IN FACT, THAT DIFFERENT  
22 ASPECTS OF PROGRAMMATIC REVIEW MIGHT CARRY HUGELY  
23 DIFFERENT WEIGHT DEPENDING ON THE CONTEXT.

24 SO I'M NOT SURE THAT YOU REALLY WANT TO DO  
25 ANYTHING THAT FORMAL IN TERMS OF CRITERIA IN

## BARRISTERS' REPORTING SERVICE

1 ADVANCE. EVEN WITHOUT CRITERIA, THE PATIENT  
2 ADVOCATES WHO WERE THERE FORM VERY FIRM OPINIONS  
3 ABOUT THE PROGRAMMATIC RELEVANCE OF A PARTICULAR  
4 PROJECT AS IT'S BEING DISCUSSED AND AT THE END OF  
5 THE DAY HAVE VERY FIRM OPINIONS ABOUT THE  
6 RELATIONSHIP BETWEEN DIFFERENT PROJECTS. AND I'M  
7 NOT SURE THAT IT'S NECESSARY TO OBJECTIFY THAT IN  
8 ADVANCE.

9 DR. OLSON: I JUST WANTED TO MAKE A  
10 COMMENT WHICH PERHAPS ADDRESSES YOUR ASSUMPTION OF  
11 THE NEED FOR ADDITIONAL MODIFICATION. I WOULD  
12 COMMENT, AND PERHAPS MR. SHEEHY, SENATOR TORRES, AND  
13 MR. KLEIN CAN CORROBORATE THIS, BUT CERTAINLY AT  
14 MANY OF THE -- ALMOST ALL OF THE GRANTS WORKING  
15 GROUP MEETINGS OVER THE PAST YEAR, I BELIEVE THERE  
16 HAS BEEN THE SCIENTIFIC MEMBERS OF THE TEAM HAVE  
17 PARTICIPATED FULLY IN THE PROGRAMMATIC REVIEW, AND  
18 THEY DO CONSIDER A PART OF IT. THEY DO NOT RUN OFF  
19 TO DO THE THING.

20 I WOULD ALSO REMIND -- I MEAN I DON'T  
21 THINK I NEED TO REMIND THE BOARD, BUT OBVIOUSLY NOT  
22 JUST AT THE GRANTS WORKING GROUP, BUT THAT IS  
23 SOMETHING THE BOARD -- IT FALLS WITH THE PURVIEW OF  
24 THE BOARD AS WELL, THE PROGRAMMATIC CONSIDERATIONS.  
25 SO THERE ARE ACTUALLY SEVERAL OPPORTUNITIES AT WHICH

## BARRISTERS' REPORTING SERVICE

1 THESE CONSIDERATIONS CAN BE BROUGHT TO BEAR AND  
2 DISCUSSED.

3 DR. FRIEDMAN: I THINK THAT THE CHALLENGE  
4 OF FORMALIZING THE PROGRAMMATIC DESIRES IS REAL, BUT  
5 I'D LIKE TO ARGUE TO PLEASE TRY AND DO IT BECAUSE  
6 THERE ARE A LOT OF VALUABLE AND WORTHWHILE GOALS  
7 THAT COMPETE WITH ONE ANOTHER. AND I THINK IT WOULD  
8 BE BETTER FOR US TO STATE THOSE FORMAL EXPECTATIONS  
9 SO WE'LL KNOW HOW TO SCORE THESE THINGS. THE  
10 DYNAMICS THAT WE'VE ALL DEALT WITH, AND I THINK  
11 REASONABLY SUCCESSFULLY, A DESIRE TO HAVE BROAD  
12 INFRASTRUCTURE BUILT THROUGHOUT THE ENTIRE STATE, A  
13 REAL SENSITIVITY TO THE NEEDS OF SO MANY DIFFERENT  
14 PATIENT POPULATIONS, BEST SCIENTIFIC OPPORTUNITIES,  
15 EXTRAORDINARY ONE-TIME CONVERGENCE OF FACTORS THAT  
16 WE TRY AND TAKE ADVANTAGE OF, THOSE ARE ALL THINGS  
17 THAT ARE DIFFICULT TO STATE BECAUSE ONE WILL COMPETE  
18 DIRECTLY WITH ANOTHER.

19 BUT I WOULD STRONGLY URGE US, PLEASE, IF  
20 WE'RE GOING TO USE -- IF WE'RE GOING TO HAVE  
21 PROGRAMMATIC PRIORITIES, AND I THINK IT'S GOOD THAT  
22 WE DO AND IT'S RIGHT THAT WE DO, THAT WE SET WHAT  
23 THOSE ARE DOWN.

24 AND I MUST SAY I AGREE WITH BOB'S POINT  
25 THAT THEY MIGHT BE SLIGHTLY DIFFERENT, THEY MIGHT BE

## BARRISTERS' REPORTING SERVICE

1 VERY DIFFERENT FROM ONE RFA TO ANOTHER, BUT I THINK  
2 IT'S REALLY WORTHWHILE TO PUT THEM IN. OTHERWISE  
3 I'M AFRAID WE LET EMOTIONS AND OTHER THINGS DICTATE  
4 DECISIONS. AND THAT'S OKAY. WE'RE NOT DOING THIS  
5 DISPASSIONATELY. WE'RE DOING IT WITH COMPASSION AND  
6 CARE, BUT WE'VE GOT -- I THINK WE HAVE TO TRY AND  
7 MAKE IT AS OBJECTIVE AND CLEAR AS WE CAN. THANK  
8 YOU.

9 CHAIRMAN SHEEHY: DR. OLSON HAD ANOTHER  
10 COMMENT.

11 DR. OLSON: I JUST WANTED TO MAKE THE  
12 COMMENT THAT ACTUALLY IN EACH RFA WE DO AT LEAST PUT  
13 IN POTENTIAL POSSIBLE PROGRAMMATIC CONSIDERATIONS  
14 THAT TEND TO DO WITH MEETING THE OBJECTIVES OF THE  
15 RFA. SO IF I JUST MIGHT GIVE THE BOARD AN EXAMPLE.  
16 FOR THE IMMUNOLOGY PROGRAM, IT WAS THE APPROPRIATE  
17 BALANCE AMONG APPLICATIONS ADDRESSING THE FOCUS  
18 AREAS OF STEM CELL TRANSPLANTATION IMMUNOLOGY  
19 RESEARCH, THOSE FOCUS AREAS WERE PRESENTED TO THE  
20 BOARD AS PART OF THE CONCEPT PLAN. SO PROGRAMMATIC  
21 CONSIDERATION COULD BE THAT BALANCE.

22 WE ALWAYS INCLUDE OTHER CONSIDERATIONS  
23 FROM THE PERSPECTIVE OF THE PATIENT ADVOCATES. THE  
24 APPROPRIATE BALANCE BETWEEN INNOVATION, RISK, AND  
25 FEASIBILITY. AND I THINK, AS I SAY, I BELIEVE THESE

## BARRISTERS' REPORTING SERVICE

1 ARE ADEQUATELY ADDRESSED BY THE VICE CHAIR IN THE  
2 CONTEXT OF PROGRAMMATIC DISCUSSION AT THE GRANTS  
3 WORKING GROUP. SO THAT'S AN EXAMPLE.

4 I'M JUST SAYING THERE ARE COMPARABLE TYPES  
5 OF GENERAL PROGRAMMATIC CRITERIA THAT ARE PUT FORTH  
6 IN THE APPLICATION USUALLY BASED ON THE OBJECTIVE --  
7 BASED ON THE OBJECTIVES OF THE RFA THAT ARE APPROVED  
8 BY THE BOARD AS PART OF THE CONCEPT PLAN.

9 CHAIRMAN SHEEHY: SO DO WE HAVE ADDITIONAL  
10 COMMENT?

11 DR. LEVIN: CAN I CLARIFY PAT'S COMMENT?  
12 SO YOU'RE SAYING YOU FEEL THAT THE PROGRAMMATIC  
13 REVIEW IS ALREADY WELL BUILT INTO THE SCIENTIFIC  
14 REVIEW PROCESS, AND AS SUCH IS REFLECTED IN WHATEVER  
15 THE SCORE THAT COMES OUT OF THE GRANTS WORKING GROUP  
16 IS?

17 CHAIRMAN SHEEHY: I THINK HER POINT WOULD  
18 BE THAT IT'S REFLECTED IN THE RECOMMENDATIONS THAT  
19 COME FROM THE GRANTS WORKING GROUP.

20 CHAIRMAN KLEIN: IT OCCURS AFTER THE  
21 SCORING.

22 CHAIRMAN SHEEHY: SO IT'S REFLECTED IN THE  
23 RANK ORDER OF THE APPLICATIONS THAT COME TO THE  
24 BOARD WHERE THERE IS SOME MOVEMENT IN VIRTUALLY --  
25 AT THE END OF EVERY REVIEW.

## BARRISTERS' REPORTING SERVICE

1 DR. LEVIN: AS I UNDERSTOOD IT, THE POINT  
2 OF THIS AGENDA ITEM WAS TO CLARIFY THAT FOR THE  
3 BOARD WHEN THAT HAPPENED AND TO BASICALLY GIVE IT A  
4 NUMERICAL SCORE OR TO GIVE IT A LITTLE BIT MORE --  
5 GIVE US AN UNDERSTANDING OF WHY AND WHEN THAT  
6 HAPPENED BECAUSE THE BOARD SOMETIMES MOVES THINGS UP  
7 AND DOWN PROGRAMMATICALLY ALMOST IN THE DARK.

8 DR. STEWARD: JUST TO AMPLIFY, I THINK ALL  
9 OF THAT IS TRUE. AND IT ACTUALLY IN A SENSE JUST  
10 MAKES THE PROCESS KIND OF A FORMAL STEP. BUT REALLY  
11 THERE IS THE ADDITIONAL RATIONALE, JUSTIFICATION,  
12 WHATEVER THAT IT DOES REALLY EMPHASIZE THAT THE  
13 PROGRAMMATIC PART OF THE REVIEW PROCESS AT THE LEVEL  
14 OF THE SCIENTIFIC WORKING GROUP IS EVERY BIT AS  
15 IMPORTANT AS THE SCIENTIFIC SCORING. AND THAT IT  
16 REALLY IS A PROCESS THAT CAN BE QUANTIFIED AND IS  
17 FORWARDED TO THE BOARD, NOT JUST IN TERMS OF THE  
18 FINAL SCORE AND FINAL POSITION, BUT ALSO MAYBE IN  
19 TERMS OF THE HETEROGENEITY OF SCORES. I THINK THAT  
20 THAT'S ONE OF THE LESSONS THAT WE'VE LEARNED, THAT  
21 KNOWING THAT HETEROGENEITY IS ACTUALLY VERY USEFUL.

22 JEFF, YOU HAVEN'T REALLY SAID VERY MUCH.  
23 I'D BE CURIOUS WHAT YOUR COMMENTS WERE AS FAR AS  
24 THAT ASPECT OF IT.

25 CHAIRMAN SHEEHY: HONESTLY, I DON'T -- MY

## BARRISTERS' REPORTING SERVICE

1 DIFFICULTY IS THE OBJECTIVITY ASPECT OF THIS. I'VE  
2 ALWAYS SAID, HAVING CHAIRED THE PROGRAMMATIC REVIEW,  
3 AND I'VE HAD DISCUSSIONS WITH STAFF AND DURING THE  
4 REVIEW WITH OTHER PATIENT ADVOCATES, WHAT ARE GOING  
5 TO BE THE PROGRAMMATIC CONSIDERATIONS. AND THAT IS  
6 AN INTUITIVE MORE THAN AN OBJECTIVE PROCESS AND  
7 REFLECTS, I THINK, KIND OF THE NATURE OF  
8 PROGRAMMATIC REVIEW.

9 PEOPLE SIT IN A REVIEW, THEY HEAR ISSUES,  
10 THEY COME UP, SOMETIMES IT'S VERY STRAIGHTFORWARD.  
11 WE'RE NOT REPRESENTED IN THIS DISEASE. SOMETIMES  
12 IT'S VERY STRAIGHTFORWARD. WITH TOOLS AND  
13 TECHNOLOGY, FOR INSTANCE, WHERE WE WERE TRYING TO  
14 HIT FIVE DIFFERENT TYPES OF APPROACHES. BUT IN  
15 OTHER INSTANCES IT'S MORE NUANCED. AND I WORRY  
16 ABOUT OBJECTIFYING A PROCESS THAT IS MORE ORGANIC  
17 AND INTUITIVE AND REFLECTS A SENSE OF EVERYBODY  
18 SITTING IN THAT ROOM. SOMETIMES IT GOES ON FOR TWO  
19 DAYS BEFORE THEY COME TO PROGRAMMATIC REVIEW. AND  
20 THEY GET A FEEL, AND THEY KIND OF LIKE CERTAIN  
21 APPROACHES AND CERTAIN SCIENCE, AND THEY, YOU KNOW,  
22 SOMETIMES -- AND THEY DO MAKE EXTRA JUDGMENTS.

23 I JUST THINK ONE OF THE DIFFICULTIES WITH  
24 PROGRAMMATIC REVIEW, I THINK PART OF IT'S BEEN -- IS  
25 BEING ADDRESSED WITH DR. SLADEK, AND I'M VERY

## BARRISTERS' REPORTING SERVICE

1 GRATEFUL FOR HIS PARTICIPATION IN KIND OF SETTING UP  
2 WHAT IT'S ABOUT AT THE BEGINNING OF THE MEETING AND  
3 BEFORE WE DO PROGRAMMATIC REVIEW, AND I THINK HE'S  
4 BEEN VERY HELPFUL. THAT DEFINITELY HELPS. AND WE  
5 CAN'T CONTROL FOR THIS AND I DON'T THINK WE SHOULD.

6 IT OFTEN DEPENDS ON THE ACTING CHAIR OF  
7 THAT REVIEW SESSION. SOME ACTING CHAIRS WHO HAVE  
8 BEEN INVOLVED WITH OUR PROCESS A LOT ARE VERY ACTIVE  
9 IN PROGRAMMATIC REVIEW, AND THEY CAN REALLY CHANGE  
10 AND INNERVATE THE PROCESS. OTHERS NOT THAT FAMILIAR  
11 WITH OUR PROCESS OR MAYBE NOT THAT KEEN ON  
12 PROGRAMMATIC REVIEW, THEY OFFER A DIFFERENT TEXTURE.

13 BUT, AGAIN, THOSE CHAIRS WERE CHOSEN  
14 BECAUSE OF THEIR EXPERTISE. I DON'T WANT TO SAY  
15 CHOOSE A DIFFERENT CHAIR. I THINK SOME OF THIS  
16 VARIATION, THIS VARIABILITY IS BENEFICIAL TO US AS  
17 AN ENTITY. I THINK TOO MUCH -- WHEN YOU GO DOWN A  
18 REALLY WELL-DRAWN PATH, I THINK YOU TEND TO LOSE  
19 SOMETHING. AND REVIEWS ARE GOING TO BE DIFFERENT.

20 A LOT OF YOU PARTICIPATE IN SCIENTIFIC  
21 REVIEWS ALL THE TIME, AND I JUST THINK THAT EACH ONE  
22 HAS ITS OWN CHARACTER. I DON'T KNOW IF OBJECTIFYING  
23 THIS PROCESS WILL HELP TO MAINTAIN AND KEEP A GOOD  
24 SPIRIT, OR IT MIGHT BE A LIMITATION ON THE FREE FLOW  
25 OF THE DISCUSSION AND THE KIND OF INTUITIVE, ORGANIC

## BARRISTERS' REPORTING SERVICE

1 WAY IN WHICH THESE RECOMMENDATIONS, WHICH ARE  
2 OBJECTIVE. THE RECOMMENDATIONS THAT COME OUT AT THE  
3 END ARE OBJECTIVE. THEY'RE RANKED, THEY MOVE STUFF  
4 UP AHEAD OF OTHER STUFF. THERE'S USUALLY SOME  
5 FAIRLY GOOD CONTEXT FROM THE WORKING GROUP ON WHY  
6 THEY MOVED STUFF UP.

7 SO THE BOARD'S GENERALLY BEEN AMENABLE TO  
8 STUFF THAT'S BEEN MOVED UP.

9 MR. ROTH: JEFF, IS THERE A REPORT ABOUT  
10 THAT?

11 CHAIRMAN SHEEHY: ON HOW IT WORKS?

12 MR. ROTH: NO, JUST WHEN YOU HAVE THAT  
13 DISCUSSION AND YOU MOVE THINGS AROUND, DOES ANYBODY  
14 TAKE NOTES AND ACTUALLY REPORT ON WHY THINGS WERE  
15 DONE?

16 DR. OLSON: WHENEVER THERE IS A  
17 PROGRAMMATIC DISCUSSION, THAT IS CAPTURED, THAT  
18 DISCUSSION IS CAPTURED AT THE END OF THE SUMMARY.

19 MR. SWEEDLER: AND JUST TO PROVIDE SOME  
20 ADDITIONAL DETAIL ABOUT HOW THAT LOOKS, THE MOTION  
21 THAT WAS MADE IS ALWAYS DESCRIBED, THE ARGUMENTS  
22 THAT WERE GIVEN BACK AND FORTH, AND THE VOTE THAT  
23 WAS TAKEN ON THAT MOTION. SO THE OUTPUT, THE VIEWS  
24 OF THE RANGE OF MEMBERS OF THE GRANTS WORKING GROUP,  
25 THERE'S AN ATTEMPT TO CAPTURE THAT AND EXPRESS THAT

## BARRISTERS' REPORTING SERVICE

1 IN THE SUMMARY TO THE BOARD.

2 MR. ROTH: THE SUMMARIES ONE BY ONE, BUT I  
3 WAS LOOKING MAYBE IT WOULD BE HELPFUL, I DON'T KNOW  
4 IF THIS IS WHERE YOU WERE GOING WITH THIS, OS, BUT  
5 JUST INSTEAD OF HAVING TO LOOK FOR THOSE ONE BY ONE  
6 THROUGH A LOT OF GRANTS, IT MIGHT BE HELPFUL. JEFF,  
7 YOU DO A NICE JOB USUALLY OF TALKING ABOUT THAT, BUT  
8 IT MIGHT BE INTERESTING TO HAVE SORT OF A REPORT  
9 ABOUT WHAT THE PROGRAMMATIC DISCUSSION WAS SO WE  
10 HAVE A FLAVOR FOR IT.

11 CHAIRMAN SHEEHY: NO.

12 MR. ROTH: THE CONTEXT OF THE ROOM IS VERY  
13 IMPORTANT.

14 CHAIRMAN KLEIN: YOU MEAN A PARAGRAPH OR  
15 SOMETHING?

16 MR. ROTH: YES.

17 CHAIRMAN KLEIN: JUST TO CAPTURE, DUANE,  
18 YOUR COMMENT IN TRYING TO CAPTURE THE ESSENCE OF IT  
19 AND IN FOLLOWING ON JEFF'S COMMENT, ONE OF THE  
20 THINGS -- PROBLEMS WITH THE SCORING SYSTEM, IF YOU  
21 HAD FIVE SCORING CATEGORIES FOR EACH RFA AND YOU HAD  
22 DISTRIBUTION OF POINTS BETWEEN THEM, IT WOULDN'T  
23 CAPTURE, FOR EXAMPLE, THAT IN PROGRAMMATIC IT CAME  
24 UP THAT THIS WAS A PIVOTAL -- IT WAS A HIGH RISK  
25 ITEM. IT HAD BEEN SCORED DOWN BECAUSE IT WAS SUCH

## BARRISTERS' REPORTING SERVICE

1 HIGH RISK AND HIGH AMBITION. BUT IF THEY COULD MAKE  
2 THIS DISCOVERY BE SO PIVOTAL FOR THIS PARTICULAR  
3 FIELD, SO THAT THE WHOLE PROGRAMMATIC DECISION WAS  
4 SWAYED ON HOW PIVOTAL THAT DISCOVERY WOULD BE AND  
5 HOW IMPORTANT THE IMPORTANCE OF THE WORK ITSELF.

6 SO, FOR EXAMPLE, TO GET A PARKINSON'S CELL  
7 LINE THAT COULD BE USED BY LARGE NUMBERS OF  
8 RESEARCHERS COULD BE PIVOTAL TO PARKINSON'S RESEARCH  
9 MOVING FORWARD AND HAVING STANDARD  
10 CHARACTERIZATIONS, AND THAT SPECIFIC FACT COULD  
11 COMPENSATE FOR A LOT OF RISK AND LOT OF OTHER  
12 ISSUES. THE QUESTION IS I DO THINK MAYBE  
13 FORMALIZING THE COMMENT, AS DUANE SUGGESTS, AND  
14 CAPTURING THE ESSENCE OF THE DISCUSSION REALLY  
15 PROVIDES THE INSIGHT TO THE DISCUSSION BETTER THAN  
16 HAVING A WHOLE SCORING SYSTEM.

17 AND THE QUESTION WITH THE SCORING SYSTEM  
18 IS THE, YOU KNOW, THE SCORE IF IT WAS TAKEN DURING  
19 THE SESSION, AND I WILL SAY THE SCIENTISTS HAVE BEEN  
20 GREAT IN BEING AND STAYING AND PARTICIPATING IN THIS  
21 DISCUSSION FULLY, BUT WHAT I WOULD SAY IS THAT WOULD  
22 YOU TABULATE THE SCORES AT THE VERY END? AND IF YOU  
23 TABULATE THE SCORES AT THE VERY END, THE ONLY THING  
24 YOU COULD DO IS THEN PASS ON THE SCORE TO THE BOARD;  
25 WHEREAS, IF YOU HAVE JUST A PARAGRAPH THAT CAPTURES

## BARRISTERS' REPORTING SERVICE

1 THE ESSENCE OF IT, INSTEAD OF A SCORE, IT GIVES YOU  
2 AN INFORMED INSIGHT INTO THE ESSENCE OF THE  
3 DISCUSSION.

4 DR. LEVIN: I AGREE. I HAVE TO AGREE WITH  
5 BOB AND DUANE ON THIS, THAT WE NEED MORE  
6 INFORMATION. I ASSUME THAT'S WHAT THIS ENTIRE  
7 PROCESS IS ABOUT TODAY IS TO TRY AND GET MORE  
8 INFORMATION TO THE BOARD ABOUT THE SCORING AND THE  
9 DECISION-MAKING PROCESS. AND I FIND AT LEAST WITH  
10 THE SUMMARIES THAT THERE ISN'T ENOUGH THERE TO  
11 REALLY UNDERSTAND WHY THINGS WERE MOVED  
12 PROGRAMMATICALLY. IT USUALLY SAYS SOMETHING LIKE A  
13 MOTION WAS MADE TO MOVE THIS GRANT UP  
14 PROGRAMMATICALLY AND IT FAILED SEVEN TO FIVE, AND  
15 THAT'S ABOUT IT. AND IT DOESN'T SAY WHY OR IS IT  
16 BECAUSE IT WAS TOO RISKY OR WAS IT BECAUSE THERE WAS  
17 SOME SCIENTIFIC PROBLEMS. AND IT WOULD BE REALLY  
18 USEFUL TO GET, NOT ONLY MORE INFORMATION ON THAT  
19 INDIVIDUAL GRANT, BUT, AS DUANE SUGGESTED,  
20 INFORMATION ABOUT THE CONTEXT, THE TEXTURE OF THE  
21 DISCUSSION AS A WHOLE THAT WAS SAID IF THERE WAS  
22 SOME DISEASES THAT WERE BETTER REPRESENTED OR OTHERS  
23 THAT WEREN'T OR SOME PARTICULAR CONFLAGRATION OF  
24 GREAT OPPORTUNITIES THAT CAME TOGETHER THAT MADE  
25 PEOPLE WANT TO MOVE THINGS UP OR DOWN TO MAKE ROOM

## BARRISTERS' REPORTING SERVICE

1 FOR OTHERS. IT WOULD BE REALLY USEFUL TO EVEN GET A  
2 COUPLE OF PARAGRAPHS ABOUT THAT DISCUSSION IN THE  
3 SUMMARY REPORT OR OVERALL FOR THE WHOLE GRANTS  
4 WORKING GROUP SESSION FOR THAT RFA.

5 MS. SAMUELSON: I'M WONDERING IF WE MIGHT  
6 NOT HAVE THE DISCUSSION AT THE BEGINNING OF THE  
7 MEETING BECAUSE IT SHOULD, I THINK, BE INFORMING THE  
8 SCIENTIFIC MERIT VOTING AS WELL AS THE PROGRAMMATIC  
9 SESSION.

10 CHAIRMAN KLEIN: JOAN, IT IS INTENDED --  
11 THERE'S TWO THINGS THAT YOU MAY BE ADDRESSING.  
12 HAVING A DISCUSSION AT THE BEGINNING OF THE SESSION  
13 ON PROGRAMMATIC CONSIDERATIONS, IS THAT WHAT YOU'RE  
14 SAYING?

15 MS. SAMUELSON: YEAH. YES.

16 CHAIRMAN KLEIN: WELL, LAYING OUT  
17 PROGRAMMATIC CONSIDERATIONS FOR CONSIDERATION DURING  
18 THE PROGRAMMATIC PORTION IN A DISCUSSION, MY  
19 UNDERSTANDING IS DR. SLADEK IS DOING A VERY GOOD JOB  
20 NOW OF ENHANCING THIS PROCESS BY DESCRIBING  
21 ELEMENTS, WHO ALL THE PARTICIPANTS ARE AND WHAT  
22 THEIR ROLES ARE. AND IT COULD BE ADDED TO THAT  
23 PORTION OF IT, BUT THE SCIENTIFIC SCORES ARE REALLY  
24 INTENDED TO BE THE SCIENTIFIC SCORES. AND THE  
25 PROGRAMMATIC PORTION IS TO CONSIDER THE PROGRAMMATIC

## BARRISTERS' REPORTING SERVICE

1 CONSIDERATIONS. BUT LETTING THEM KNOW IN GREATER  
2 DETAIL AT THE BEGINNING OF EACH SESSION WHAT THE  
3 PROGRAMMATIC CONSIDERATIONS ARE THEY'RE GOING TO BE  
4 LOOKING AT LATER, REMINDING THEM OF THAT IS  
5 SOMETHING GIL TRIES TO DO AND DR. SLADEK COULD  
6 SUPPLEMENT IT. JEFF, WHAT DO YOU THINK?

7 MS. SAMUELSON: JUST A SECOND. LET ME ASK  
8 SOMETHING ELSE. IF IT'S BALANCING THE PORTFOLIO,  
9 MAYBE YOU'RE RIGHT AND MAYBE THAT BELONGS TOWARD THE  
10 END. BUT ISSUES OF WHETHER A GIVEN GRANT COULD BE  
11 ADVANCING OUR SCIENTIFIC AGENDA AND THE CURES AGENDA  
12 FASTER THAN, SAY, SOME OTHER FOCUS IS PART OF THE  
13 SCIENTIFIC MERIT OF THE APPLICATION. DON'T YOU  
14 THINK?

15 CHAIRMAN SHEEHY: I THINK THAT THAT'S  
16 BUILT INTO THE RFA. AND THE PURPOSE OF THE RFA, I  
17 THINK, IS DISCUSSED BEFORE WE DO THE SCIENTIFIC  
18 SCORING. SO I DON'T KNOW -- I DON'T KNOW IF THAT  
19 WOULD -- I REALLY --

20 MS. SAMUELSON: IT'S DOUBLING UP OR  
21 SOMETHING. WELL, I THINK IT IS IN THE RFA, BUT I  
22 GUESS I'M PERCEIVING A PROBLEM AND SEEING THIS AS A  
23 POSSIBLE SOLUTION. BECAUSE ALL ALONG IT JUST SEEMED  
24 TO ME THAT THERE'S KIND OF A CHRONIC PROBLEM THAT  
25 THE RISKS OF A GIVEN GRANT ARE ALWAYS DISCUSSED IN

## BARRISTERS' REPORTING SERVICE

1     DETAIL, BUT THE REWARDS ARE NOT.  AND THAT'S KIND OF  
2     PUT OFF.  OH, WELL, THAT'S A PROGRAMMATIC ISSUE  
3     WHEN, IN FACT, WHAT THAT DOES IS SKEW THE SCORES.  I  
4     THINK WE'VE SEEN THAT ROUTINELY, THAT MORE  
5     TRANSLATIONAL GRANTS DON'T SCORED AS WELL.  I THINK  
6     THAT'S A BIG PART OF WHY.

7             SO HAVING THIS BE PART OF THE DISCUSSION  
8     AND REALLY FOCUSED ON AT THE BEGINNING WILL PUT THAT  
9     IN A CONTEXT FOR THE SCIENTIFIC MERIT AS WELL.  AND  
10    I PERCEIVE ANOTHER PROBLEM WHICH IT COULD HELP SOLVE  
11    WHICH IS WE HAVE FEWER AND FEWER SCIENTISTS WHO ARE  
12    FAMILIAR WITH OUR PROCESS INSTEAD OF THE WAY I THINK  
13    THE SYSTEM WAS ORIGINALLY INTENDED TO WORK WHERE  
14    WE'RE ALL WORKING TOGETHER AND GETTING MORE FAMILIAR  
15    WITH THE PROCESS.  WE'VE HAVING MORE AND MORE  
16    SCIENTISTS WHO HAVEN'T BEEN A PART OF THE PROCESS.  
17    SO THIS IS UNFAMILIAR TO THEM, AND THERE'S BEEN  
18    QUITE A BIT OF CRITICISM OF THE PROGRAMMATIC PROCESS  
19    AND THAT IT'S SOMEHOW TAINTING THE SCIENTIFIC MERIT.

20            DR. STEWARD:  I JUST WANT TO SAY THAT  
21    REALLY IT WAS THIS KIND OF CONCERN THAT REALLY  
22    TRIGGERED ME TO START THINKING ABOUT THIS IN THE  
23    BEGINNING.  THE SCIENTIFIC REVIEW GROUP IS DOING A  
24    SPECTACULAR JOB REVIEWING THE SCIENCE.  THERE IS A  
25    NEED TO BRING IN NEW MEMBERS OF THE SCIENTIFIC

## BARRISTERS' REPORTING SERVICE

1 REVIEW GROUP TO COVER THE WATERS IN TERMS OF  
2 EXPERTISE. BUT THE CONSEQUENCE OF THAT IS -- AND  
3 ESPECIALLY WHEN THERE'S NOT SOME KIND OF THREAD  
4 THROUGH IT. SO IF, JOHN, FOR EXAMPLE, WAS ALWAYS  
5 THE CHAIR AND COULD LEAD THE DISCUSSION ALWAYS, THAT  
6 WOULD SOLVE THE PROBLEM IMMEDIATELY. BUT WHEN  
7 THERE'S A DIFFERENT CHAIR AND PERHAPS EVEN A LARGELY  
8 DIFFERENT GROUP, THE WHOLE PROCESS OF PROGRAMMATIC  
9 REVIEW OR SORT OF PATIENT ADVOCATE'S VIEWPOINT, I  
10 THINK SOMETIMES IT MAY NOT BE SEEN IN THE SAME WAY  
11 AS IT IS WITH THE CORE COMMITTEE.

12 IN SOME WAY FURTHER SORT OF INSTANTIATING  
13 THE PROCESS WOULD HELP TO SOLVE THAT PROBLEM. THAT  
14 REALLY WAS THE MOTIVATION FOR MY STARTING TO THINK  
15 ABOUT THIS IN THE BEGINNING. I DON'T THINK IT  
16 REALLY MAKES TOO MUCH DIFFERENCE WHAT KIND OF  
17 PROCESS WE USE, BUT JUST SOMETHING TO REALLY MAKE IT  
18 INTO A CLEAR PROCESS.

19 CHAIRMAN SHEEHY: MAYBE IF I COULD KIND OF  
20 CUT TO THE CHASE BECAUSE I DON'T THINK WE'RE GOING  
21 TO GET TO A DECISION POINT TODAY. SO MAYBE I CAN  
22 IDENTIFY THREE POINTS FOR FURTHER STUDY.

23 ONE IS THE POTENTIAL FOR A REPORT BACK  
24 FROM THE GRANTS WORKING GROUP ON PROGRAMMATIC  
25 REVIEW, AND MAYBE I CAN TALK TO STAFF. I DON'T WANT

## BARRISTERS' REPORTING SERVICE

1 TO PUT THEM UNDER THE GUN, BUT SEE WHAT MIGHT BE  
2 FEASIBLE IN TERMS OF AN ACTUAL REPORT ON THE  
3 PROGRAMMATIC REVIEW THAT MAYBE STANDS SEPARATE FROM  
4 EACH APPLICATION SO PEOPLE CAN KIND OF GET A TEXTURE  
5 OF THE REVIEW AND GET A SENSE OF WHAT HAPPENED. YOU  
6 KNOW, THIS IS SOMETHING I WANT TO TALK TO STAFF  
7 ABOUT AND MAKE SURE. IT IS A BURDEN ON STAFF, BUT I  
8 THINK IT MAY BE JUST SIMPLY COLLATING THE DIFFERENT  
9 PIECES OF INFORMATION THAT THEY HAVE IN FRONT OF  
10 THEM INTO A REPORT. SO THAT'S ONE, A REPORT, WHICH  
11 IS WHAT I THINK IS WHAT DUANE AND JACOB WERE LOOKING  
12 FOR.

13 MR. ROTH: JEFF, I APOLOGIZE. I HAVE TO  
14 GO OFF, BUT I THINK THAT MIGHT SOLVE EVEN THE  
15 FOLLOW-ON ONES THAT ARE COMING. IF THERE IS A  
16 REPORT, THAT MEANS IT HAS TO BE FOCUSED ON BECAUSE  
17 YOU HAVE WRITE IT AND THERE HAS TO BE THE  
18 DISCUSSION. ANYWAY, I'M GOING TO GET OFF. IS THERE  
19 ANOTHER VOTE THAT WE HAVE TO TAKE YOU NEED ME FOR?

20 MS. KING: YES, FOR ITEM NO. 5, WHICH WE  
21 COULD PROBABLY DO RELATIVELY QUICKLY.

22 MR. ROTH: SO I'LL HANG ON. I CAN DO  
23 ANOTHER FIVE MINUTES OR SO.

24 CHAIRMAN SHEEHY: SO WHAT I'LL DO, I'LL  
25 IDENTIFY THESE THREE QUESTIONS. UNLESS SOMEBODY HAS

## BARRISTERS' REPORTING SERVICE

1 SOMETHING THEY REALLY NEED TO SAY, WE CAN GET OUT.  
2 WE'LL MOVE ON.

3 THE SECOND THING TO CONSIDER IS IF THERE  
4 ARE SOME CRITERIA THAT MIGHT PROVIDE SOME BASIS FOR  
5 AN OBJECTIVE ANALYSIS. AND EVEN IF THEY MAY NOT BE  
6 FOR OBJECTIVE ANALYSIS, THEY COULD SERVE AS A  
7 DIRECTION TO THE GRANTS WORKING GROUP BEFORE WE  
8 START THE MEETING.

9 THE THIRD IS WHAT IS THE DISCUSSION ABOUT  
10 THE PROGRAMMATIC ISSUES THAT JOAN AND OS HAVE BEEN  
11 TALKING ABOUT THAT SHOULD BE GIVEN TO THE COMMITTEE  
12 BEFORE IT STARTS BY DR. SLADEK TO MAKE SURE THAT WE  
13 HAVE A FAIRLY UNIFORM SORT OF INSTRUCTIONS.

14 ARE PEOPLE COMFORTABLE WITH THOSE BEING  
15 THE THREE AVENUES THAT WE KIND OF CARRY THIS FORWARD  
16 FOR FURTHER INFORMATION?

17 CHAIRMAN KLEIN: IN 30 SECONDS, JEFF, WE  
18 SHOULD REMIND EVERYONE THAT JAMES HARRISON HAS  
19 MATERIALS IN PROGRESS TO RESPOND TO THIS SAME POINT,  
20 AND IT RELATES TO YOUR THIRD POINT, I THINK, JEFF,  
21 THAT WILL PROVIDE A FORMAL DISCUSSION OF THE ROLES  
22 OF THE PATIENT ADVOCATES WITHIN THE PROCESS AND THE  
23 ROLES OF STAFF IN SUPPORTING THE PROCESS SO THAT AS  
24 WE GO TO IMMUNOLOGY OR DISEASE TEAMS OR, YOU KNOW,  
25 TOOLS, WE HAVE DIFFERENT SPECIALIZED GROUPS THAT ARE

## BARRISTERS' REPORTING SERVICE

1 NOT AS FAMILIAR WITH THE PROCESS, AND THIS WILL HELP  
2 THEM UNDERSTAND AND FULLY PARTICIPATE.

3 CHAIRMAN SHEEHY: OKAY. I DON'T THINK WE  
4 NEED PUBLIC COMMENT. WE'RE NOT TAKING ACTION. I'M  
5 GOING TO GO AHEAD TO ITEM 5.

6 MS. KING: THIS IS AN ITEM THAT HAS BEEN  
7 BEFORE THIS SUBCOMMITTEE, A RELATED ITEM AND THEN  
8 FOR THE BOARD. AND WHAT THE SUBCOMMITTEE IS LOOKING  
9 TO DO AT THIS POINT IS DISCUSS FORMALIZING A  
10 PROCESS, GOING A LITTLE BIT FURTHER THAN WHAT WAS  
11 VOTED ON BY THE BOARD AT THE BOARD MEETING IN  
12 AUGUST.

13 CHAIRMAN SHEEHY: JAMES, COULD YOU RUN US  
14 THROUGH THIS QUICKLY?

15 MR. HARRISON: SURE. SO JUST TO BE CLEAR,  
16 AS MELISSA SAID, THE BOARD DID VOTE ON A PROCESS OR  
17 RATHER AN EXISTING POLICY IN THE GRANTS  
18 ADMINISTRATION POLICY RELATING TO THE USE OF UNUSED  
19 DISEASE TEAM RESEARCH I AWARD FUNDS AND HUMAN  
20 CLINICAL TRIALS. SO THAT'S NOT AT ISSUE HERE.

21 WHAT WE'RE ATTEMPTING TO DISCUSS HERE IS  
22 THE BROADER POLICY IMPLICATIONS GOING FORWARD FOR  
23 FUTURE AWARD PROGRAMS WHEN AN APPLICANT PROPOSES A  
24 CHANGE IN SCOPE OF HIS OR HER RESEARCH PROPOSAL TO  
25 INCLUDE RESEARCH INVOLVING -- CLINICAL RESEARCH

## BARRISTERS' REPORTING SERVICE

1 INVOLVING HUMANS. SO IT'S LIMITED TO SITUATIONS  
2 WHERE HUMAN CLINICAL TRIAL RESEARCH WAS NOT INCLUDED  
3 WITHIN THE SCOPE OF THE ORIGINAL APPLICATION, BUT  
4 DUE TO THE SUCCESS OF THE RESEARCH, THE APPLICANT  
5 HAS LEFT-OVER FUNDS AND WISHES TO CHANGE THE SCOPE  
6 OF THE APPLICATION IN ORDER TO USE THOSE FUNDS ON  
7 HUMAN CLINICAL RESEARCH.

8 AND THE PROPOSAL UNDER THOSE CIRCUMSTANCES  
9 IS TO HAVE THE BOARD APPROVE AT A CONCEPT LEVEL THE  
10 REQUEST FOR A CHANGE IN SCOPE TO PERMIT THE USE OF  
11 THOSE UNUSED FUNDS FOR HUMAN CLINICAL TRIAL  
12 RESEARCH.

13 CHAIRMAN SHEEHY: THANKS, JAMES. AND JUST  
14 TO GIVE A CONTEXT, I THINK THAT THERE WERE A LOT OF  
15 MEMBERS WITHIN THE LARGER ICOC WHO WERE NOT ABLE TO  
16 PARTICIPATE IN THIS DISCUSSION AND FELT THAT A  
17 PROCESS WAS NEEDED. SO IF I COULD START WITH A  
18 MOTION TO ADOPT.

19 MR. TORRES: SO MOVED.

20 CHAIRMAN SHEEHY: AND A SECOND?

21 CHAIRMAN KLEIN: SECOND.

22 CHAIRMAN SHEEHY: UNLESS PEOPLE REALLY  
23 WANT TO GET INTO THE WEEDS ON THIS, I REALLY THINK  
24 THIS IS SOMETHING THAT WE SHOULD AT LEAST REFER UP  
25 TO THE BOARD GIVEN THE HIGH INTEREST THAT WAS

## BARRISTERS' REPORTING SERVICE

1 EXPRESSED ON THE BOARD ON SOME SORT OF POLICY FOR  
2 THIS.

3 MR. ROTH: JUST QUICKLY, I'LL SUPPORT  
4 THAT, TAKE IT TO THE BOARD, BUT I DO NOT THINK THIS  
5 IS A NECESSARY CONSIDERATION. I JUST THINK IT'S  
6 ADDING ANOTHER LAYER WHERE YOU'VE GOT THE FDA AND  
7 THE IRB'S WHO ARE VERY WELL EQUIPPED TO MAKE  
8 DECISIONS ABOUT HUMAN CLINICAL TRIALS. I WOULD  
9 THINK IT'S NOT NECESSARY, BUT I DO THINK IT SHOULD  
10 GO TO THE BOARD FOR MORE DISCUSSION.

11 CHAIRMAN SHEEHY: THAT'S THE MAIN POINT,  
12 THAT WE KIND OF PULL TOGETHER A POLICY. PEOPLE MAY  
13 HAVE DIFFERENT VIEWS ON HOW WE PULL IT TOGETHER.

14 MS. SAMUELSON: THIS IS JOAN. COULD WE  
15 GET STAFF INFORMATION ON HOW MUCH DEMAND THERE HAS  
16 BEEN FOR THIS?

17 DR. LEVIN: IT HASN'T HAPPENED YET.

18 CHAIRMAN KLEIN: JUST AS AN EXAMPLE, JOAN,  
19 THIS WOULD HAPPEN IF THERE WERE AN EARLY TRANSLATION  
20 AWARD, DOESN'T PROPOSE HAVING A HUMAN CLINICAL  
21 TRIAL, THERE'S A HUGE BREAKTHROUGH, THERE'S  
22 LEFT-OVER FUNDS. VERY RARE SITUATION.

23 MS. SAMUELSON: I JUST WONDERED IF IT'S  
24 JUST THEORETICAL. OKAY. ALL RIGHT.

25 MR. ROTH: JEFF, MY VOTE IS YES. THANK

## BARRISTERS' REPORTING SERVICE

1 YOU, GUYS.

2 CHAIRMAN SHEEHY: PUBLIC COMMENT? ANY  
3 PUBLIC COMMENT IN SAN FRANCISCO? YOU WANT TO CALL  
4 THE ROLL, MELISSA.

5 MS. KING: JACOB LEVIN.

6 DR. LEVIN: YES.

7 MS. KING: MICHAEL FRIEDMAN.

8 DR. FRIEDMAN: YES.

9 MS. KING: ROBERT KLEIN.

10 CHAIRMAN KLEIN: YES.

11 MS. KING: JEANNIE FONTANA.

12 DR. FONTANA: YES.

13 MS. KING: WE HAVE DUANE ROTH'S VOTE WHICH  
14 IS YES.

15 JOAN SAMUELSON.

16 MS. SAMUELSON: YES.

17 MS. KING: JEFF SHEEHY.

18 CHAIRMAN SHEEHY: YES.

19 MS. KING: OSWALD STEWARD.

20 DR. STEWARD: YES.

21 MS. KING: ART TORRES.

22 MR. TORRES: AYE.

23 MS. KING: AND THAT MOTION CARRIES.

24 CHAIRMAN SHEEHY: OKAY. WE HAVE THE PREAP  
25 PROCESS ON HERE TODAY. DO PEOPLE HAVE THE STRENGTH

**BARRISTERS' REPORTING SERVICE**

1 FOR THAT? I KNOW WE'VE BEEN GOING ABOUT AN HOUR AND  
2 A HALF.

3 DR. FRIEDMAN: THIS IS MIKE FRIEDMAN. I'M  
4 GOING TO NEED TO LEAVE IN ABOUT FOUR MINUTES.

5 CHAIRMAN SHEEHY: A LOT OF PEOPLE HAVE 1  
6 O'CLOCKS.

7 MS. SAMUELSON: I THINK IT DESERVES MORE  
8 ATTENTION THAN WE HAVE TIME FOR.

9 CHAIRMAN SHEEHY: SO WE CAN DEFER THIS TO  
10 THE NEXT MEETING. AND UNLESS ANYONE HAS ANYTHING  
11 ELSE THEY'D LIKE TO BRING UP, I THINK THIS HAS BEEN  
12 PRODUCTIVE. AND I APPRECIATE EVERYONE'S  
13 CONTRIBUTIONS GREATLY.

14 MS. SAMUELSON: THANK YOU, JEFF.

15 CHAIRMAN SHEEHY: THANK YOU VERY MUCH.

16 (THE MEETING WAS ADJOURNED AT 12:51  
17 P.M.)

18  
19  
20  
21  
22  
23  
24  
25

## BARRISTERS' REPORTING SERVICE

### REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON WEDNESDAY, SEPTEMBER 29, 2010, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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